### SOLICITATION

#### SECTION A - SOLICITATION/CONTRACT FORM

1. Requisition or other Purchase Authority: Public Law 81-692 as amended

2. **Request for Proposal**
   - **(RFP) Number:** NIAID-DAIT-NIHAI201800018

3. **Issue Date:** August 31, 2018

4. **Set Aside:**
   - [X] No
   - [ ] Yes See Part IV Section L

5. **Title:** CIVICs Statistical, Data Management and Coordination Center (SDMCC)

6. **ISSUED BY:**
   - Office of Acquisitions
   - National Institute of Allergy and Infectious Diseases
   - National Institutes of Health
   - 5601 Fishers Lane
   - Rockville, MD 20852

7. **SUBMIT OFFERS TO:**
   - See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.

8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, “Packaging and Delivery of the Proposal,” until 3:00PM EST on November 29, 2018. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.

9. This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." If proposals are required to be delivered to two different locations, the OFFICIAL POINT OF RECEIPT for determining TIMELY DELIVERY is the address provided for the OFFICE OF ACQUISITIONS.

   IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offerors--Competitive Acquisition," LOCATED IN SECTION L.1. OF THIS SOLICITATION.

10. Offeror must be registered in the System for Award Management (SAM) prior to award of a contract. Offerors must access the CCR through The System for Award Management (SAM) at [http://www.sam.gov](http://www.sam.gov)

11. **FOR INFORMATION CALL:** Maribel Miranda
    - PHONE: 240-669-5139
    - e-MAIL: Maribel.Miranda@nih.gov
    - COLLECT CALLS WILL NOT BE ACCEPTED.

5601 Fishers Lane
Rockville, MD 20852

Tom Bahrami
Contracting Officer
Office of Acquisitions
NIAID, NIH, DHHS
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

10. Privacy Act - Treatment of Proposal Information. .......................................................... 54
11. Selection of Offerors. ........................................................................................................ 54
12. Institutional Responsibility Regarding Investigator Conflicts of Interest .............................. 55
13. Certification of Filing and Payment of Taxes. ..................................................................... 55
14. Past Performance Information. .......................................................................................... 56
15. Prohibition on Contractor Involvement with Terrorist Activities ......................................... 56
17. Electronic Information Technology Accessibility Notice, HHSAR 352.239-73 (December 2015) . 67
18. Solicitation Provisions Incorporated by Reference. .............................................................. 68
b. TECHNICAL PROPOSAL INSTRUCTIONS. ................................................................. 68
   1. Technical Discussions. ....................................................................................................... 69
   2. Other Considerations. ........................................................................................................ 72
   3. Technical Evaluation. ........................................................................................................ 72
   4. Obtaining and Disseminating Biomedical Research Resources. ........................................ 72
c. BUSINESS PROPOSAL INSTRUCTIONS. ................................................................. 74
   1. Basic Cost/Price Information. .......................................................................................... 74
   2. Proposal Cover Sheet. ...................................................................................................... 74
   3. Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data .... 74
   4. Salary Rate Limitation. .................................................................................................... 75
   5. Mentor Protege Program, HHSAR 352.219-70. ............................................................... 76
   6. HUBZone Small Business Concerns. .............................................................................. 77
   7. Total Compensation Plan. ............................................................................................... 77
   8. Other Administrative Data. ............................................................................................. 78
   9. Qualifications of the Offeror. .......................................................................................... 81
  10. Subcontractors. ................................................................................................................ 82
  12. Travel Costs/Travel Policy. ............................................................................................. 82

SECTION M - EVALUATION FACTORS FOR AWARD .......................................................... 83
   1. GENERAL. ....................................................................................................................... 83
   2. COST/PRICE EVALUATION. ....................................................................................... 83
   3. EVALUATION OF OPTIONS. ....................................................................................... 83
   4. EVALUATION OF DATA SHARING PLAN. ................................................................. 83
   5. TECHNICAL EVALUATION FACTORS. ................................................................. 84
   6. EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY- SECTION 508 ......................................................................................... 84
   7. PAST PERFORMANCE FACTOR. .................................................................................. 84
PART I - THE SCHEDULE

THE INFORMATION SET FORTH IN SECTION A - SOLICITATION/CONTRACT FORM, HEREIN CONTAINS IMPORTANT INFORMATION FOR ANY OFFEROR INTERESTED IN RESPONDING TO THIS SOLICITATION. ANY CONTRACT RESULTING FROM THIS SOLICITATION WILL INCLUDE IN ITS SECTION A - SOLICITATION/CONTRACT FORM, ACCOUNTING, APPROPRIATION AND GENERAL INFORMATION APPLICABLE TO THE CONTRACT AWARD.

THE CONTRACT SCHEDULE SET FORTH IN SECTIONS B THROUGH H, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror’s proposal and requiring Contracting Officer Prior Approval) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The objective for this contract to establish and manage a Statistical, Data Management and Coordination Center (SDMCC) that will support the Collaborative Influenza Vaccine Innovation Center’s (CIVIC) program through: facilitating statistically sound preclinical and clinical study design; enabling data analyses and data sharing across the CIVICs program; conducting/coordinating submission of CIVICs data and meta-data to NIAID-designated public repositories; developing and maintaining a CIVICs public portal; tracking and sharing of CIVICs-generated samples, reagents, resources, and standard operating procedures (SOPs) across the CIVICs program and with the broader research community; and managing initiation, conduct, and tracking of CIVICs-related clinical trials and human challenge studies.

ARTICLE B.2. ESTIMATED COST - OPTION

a. The estimated cost of the Base Period of this contract is $TBD.

b. The fixed fee for the Base Period of this contract is $TBD. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer. Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee for the Base Period is $TBD.

d. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government’s total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

<table>
<thead>
<tr>
<th></th>
<th>Estimated Cost ($)</th>
<th>Fixed Fee ($)</th>
<th>Estimated Cost Plus Fixed Fee ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base Period</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>Option Period(s)</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
</tr>
<tr>
<td>Total</td>
<td>TBD</td>
<td>TBD</td>
<td>TBD</td>
</tr>
</tbody>
</table>
ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Conferences & Meetings, 2) Food for Meals, Light Refreshments & Beverages, 3) Promotional Items, 4) Acquisition, by purchase or lease, of any interest in real property; 5) Special rearrangement or alteration of facilities; 6) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 7) Travel Costs including Foreign Travel; 8) Consultant Costs; 9) Subcontract Costs; 10) Patient Care Costs; 11) Accountable Government Property; 12) Printing costs; and 13) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.
SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. [DESCRIPTION_SPECIFICATION_WORKSTATEMENT_STATEMENT_OF_WORK]

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated August 10, 2018, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one hardcopy of each report shall be submitted to the Contracting Officer.

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: [http://www.hhs.gov/web/508/index.html](http://www.hhs.gov/web/508/index.html) under "Making Files Accessible."

All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b).

a. **Technical Progress Reports**

   1. In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award. [Note: Beginning May 25, 2008, the Contractor shall include the applicable PubMed Central or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]

      [ ] Monthly  
      [X] Quarterly  
      [ ] Semi-Annually  
      [X] Annually  
      [ ] Annually (with a requirement for a Draft Annual Report)  
      [ ] Final - Upon final completion of the contract  
      [X] Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

   2. **Summary of Salient Results**

      The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

b. **Other Reports/Deliverables**

   1. **Reporting of Financial Conflict of Interest (FCOI)**
All reports and documentation required by 45 CFR Part 94, Responsible Prospective Contractors including, but not limited to, the New FCOI Report, Annual FCOI Report, Revised FCOI Report, and the Mitigation Report, shall be submitted to the Contracting Officer in Electronic format. Thereafter, reports shall be due in accordance with the regulatory compliance requirements in 45 CFR Part 94.

45 CFR Part 94 is available at: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45. See Part 94.5, Management and reporting of financial conflicts of interest for complete information on reporting requirements.

(Reference subparagraph g. of the INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST Article in SECTION H of this contract.)

2. Source Code and Object Code

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS

INFORMATION AND/OR PHYSICAL SECURITY

A. Security Assessment and Authorization (SA&A)- A valid authority to operate (ATO) certifies that the Contractor's information system meets the contract's requirements to protect the agency data. If the system under this contract does not have a valid ATO, the Contractor (and/or any subcontractor) shall work with the agency and supply the deliverables required to complete the ATO within the specified timeline(s) within three (3) months after contract award. The Contractor shall conduct the SA&A requirements in accordance with HHS IS2P, NIST SP 800-37, Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach (latest revision). For an existing ATO, Contracting Officer Representative must make a determination if the existing ATO provides appropriate safeguards or if an additional ATO is required for the performance of the contract and state as such. NIH acceptance of the ATO does not alleviate the Contractor's responsibility to ensure the system security and privacy controls are implemented and operating effectively.

B. SA&A Package Deliverables - The Contractor (and/or any subcontractor) shall provide an SA&A package within 30 days of contract award to the CO and/or COR. The following SA&A deliverables are required to complete the SA&A package.

• System Security Plan (SSP) - due within 30 days after contract award. The SSP shall comply with the NIST SP 800-18, Guide for Developing Security Plans for Federal Information Systems, the Federal Information Processing Standard (FIPS) 200, Recommended Security Controls for Federal Information Systems, and NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline requirements, and other applicable NIST guidance as well as HHS and NIH policies and other guidance. The SSP shall be consistent with and detail the approach to IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The SSP shall provide an overview of the system environment and security requirements to protect the information system as well as describe all applicable security controls in place or planned for meeting those requirements. It should provide a structured process for planning adequate, cost-effective security protection for a system. The Contractor shall update the SSP at least annually thereafter.

• Security Assessment Plan/Report (SAP/SAR) - due 30 days after the contract award. The security assessment shall be conducted by the assessor and be consistent with NIST SP 800-53A, NIST SP 800-30, and HHS and NIH policies. The assessor will document the assessment results in the SAR.
The NIH should determine which security control baseline applies and then make a determination on the appropriateness/necessity of obtaining an independent assessment. Assessments of controls can be performed by contractor, government, or third parties, with third party verification considered the strongest. If independent assessment is required, include statement below. Thereafter, the Contractor, in coordination with the NIH shall conduct/assist in the assessment of the security controls and update the SAR at least annually.

- **Independent Assessment** - due 90 days after the contract award. The Contractor (and/or subcontractor) shall have an independent third-party validate the security and privacy controls in place for the system(s). The independent third party shall review and analyze the Security Authorization package, and report on technical, operational, and management level deficiencies as outlined in NIST SP 800-53. The Contractor shall address all "high" deficiencies before submitting the package to the Government for acceptance. All remaining deficiencies must be documented in a system Plan of Actions and Milestones (POA&M).

- **POA&M** - due 30 days after contract award. The POA&M shall be documented consistent with the HHS Standard for Plan of Action and Milestones and NIH policies. All high-risk weaknesses must be mitigated within 30 days and all medium weaknesses must be mitigated within 60 days from the date the weaknesses are formally identified and documented. The NIH will determine the risk rating of vulnerabilities. Identified risks stemming from deficiencies related to the security control baseline implementation, assessment, continuous monitoring, vulnerability scanning, and other security reviews and sources, as documented in the SAR, shall be documented and tracked by the Contractor for mitigation in the POA&M document. Depending on the severity of the risks, NIH may require designated POAM weaknesses to be Remediated before an ATO is issued. Thereafter, the POA&M shall be updated at least quarterly.

C. **Contingency Plan and Contingency Plan Test** - due 60 days after contract award. The Contingency Plan must be developed in accordance with NIST SP 800-34, Contingency Planning Guide for Federal Information Systems, and be consistent with HHS and NIH policies. Upon acceptance by the System Owner, the Contractor, in coordination with the System Owner, shall test the Contingency Plan and prepare a Contingency Plan Test Report that includes the test results, lessons learned and any action items that need to be addressed. Thereafter, the Contractor shall update and test the Contingency Plan at least annually.

- **E-Authentication Questionnaire** - The contractor (and/or any subcontractor) shall collaborate with government personnel to ensure that an E-Authentication Threshold Analysis (E-auth TA) is completed to determine if a full E-Authentication Risk Assessment (E-auth RA) is necessary. System documentation developed for a system using E-auth TA/E-auth RA methods shall follow OMB 04-04 and NIST SP 800-63, Rev. 2, Electronic Authentication Guidelines. Based on the level of assurance determined by the E-Auth, the Contractor (and/or subcontractor) must ensure appropriate authentication to the system, including remote authentication, is in-place in accordance with the assurance level determined by the E-Auth (when required) in accordance with HHS policies.

D. **POSITION SENSITIVITY DESIGNATIONS**

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR). The following position sensitivity designation levels apply to this solicitation/contract:

[ ] **Level 6: Public Trust - High Risk.** Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

[X] **Level 5: Public Trust - Moderate Risk.** Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).
Level 1: Non-Sensitive. Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

1. HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12

Roster-

a. The Contractor (and/or any subcontractor) shall submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster shall be submitted to the COR and/or CO within fourteen (14) calendar days after the effective date of this contract. Any revisions to the roster as a result of staffing changes shall be submitted within seven (7) calendar days of the change. The COR will notify the Contractor of the appropriate level of investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx.

b. If the Contractor is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate suitability level. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

c. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

d. The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

e. All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract. Contractors may begin work after the fingerprint check has been completed.

f. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.

g. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more that the cost of the additional investigation(s).

h. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

i. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.

j. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

E. CONTRACT INITIATION AND EXPIRATION
1. **General Security Requirements**- The Contractor (and/or any subcontractor) shall comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the contractor shall follow the HHS EPLC framework and methodology or in accordance with the HHS Contract Closeout Guide (2012). HHS EA requirements may be located here: [https://www.hhs.gov/ocio/ea/documents/proplans.html](https://www.hhs.gov/ocio/ea/documents/proplans.html)

2. **System Documentation**- Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-64, Security Considerations in the System Development Life Cycle, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.

3. **Sanitization of Government Files and Information**- As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) shall provide all required documentation in accordance with the NIH Media Sanitization and Disposal Policy to the CO and/or COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

4. **Notification**- The Contractor (and/or any subcontractor) shall notify the CO and/or COR and system ISSO within fifteen days before an employee stops working under this contract.

5. **Contractor Responsibilities Upon Physical Completion of the Contract**- The contractor (and/or any subcontractors) shall return all government information and IT resources (i.e., government information in non-government-owned systems, media, and backup systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor shall provide a certification that all government information has been properly sanitized and purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and/or NIH policies.

6. The Contractor (and/or any subcontractor) shall perform and document the actions identified in the NIH Contractor Employee Separation Checklist [https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf](https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf) when an employee terminates work under this contract within 2 days of the employee's exit from the contract. All documentation shall be made available to the CO and/or COR upon request.

7. **Contractor Non-Disclosure Agreement (NDA)**- Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract shall complete the NIH non-disclosure agreement [https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf](https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf), as applicable. A copy of each signed and witnessed NDA shall be submitted to the Contracting Officer (CO) and/or CO Representative (COR) prior to performing any work under this acquisition.

8. **Vulnerability Scanning Reports** The Contractor shall report the results of the required monthly special vulnerability scans no later than 10 days following the end of each reporting period. If required monthly, this report may be included as part of the Technical Progress Report. Otherwise, this report shall be submitted under a separate cover on monthly basis.

9. **Government Access for Security Assessment.** In addition to the Inspection Clause in the contract, the Contractor (and/or any subcontractor) shall afford the Government access to the Contractor's facilities, installations, operations, documentation, information systems, and personnel used in performance of this contract to the extent required to carry out a program of security assessment (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the confidentiality, integrity, and availability of federal data or to the protection of information systems operated on behalf of HHS, including but are not limited to:

   a. At any tier handling or accessing information, consent to and allow the Government, or an independent third party working at the Government's direction, without notice at any time during a weekday during regular business hours contractor local time, to access contractor and subcontractor installations, facilities, infrastructure, data centers, equipment (including but not limited to all servers, computing devices, and portable
media), operations, documentation (whether in electronic, paper, or other forms), databases, and personnel which are used in performance of the contract.

The Government includes but is not limited to the U.S. Department of Justice, U.S. Government Accountability Office, and the HHS Office of the Inspector General (OIG). The purpose of the access is to facilitate performance inspections and reviews, security and compliance audits, and law enforcement investigations. For security audits, the audit may include but not be limited to such items as buffer overflows, open ports, unnecessary services, lack of user input filtering, cross site scripting vulnerabilities, SQL injection vulnerabilities, and any other known vulnerabilities.

b. At any tier handling or accessing protected information, fully cooperate with all audits, inspections, investigations, forensic analysis, or other reviews or requirements needed to carry out requirements presented in applicable law or policy. Beyond providing access, full cooperation also includes, but is not limited to, disclosure to investigators of information sufficient to identify the nature and extent of any criminal or fraudulent activity and the individuals responsible for that activity. It includes timely and complete production of requested data, metadata, information, and records relevant to any inspection, audit, investigation, or review, and making employees of the contractor available for interview by inspectors, auditors, and investigators upon request. Full cooperation also includes allowing the Government to make reproductions or copies of information and equipment, including, if necessary, collecting a machine or system image capture.

c. Segregate Government protected information and metadata on the handling of Government protected information from other information. Commingling of information is prohibited. Inspectors, auditors, and investigators will not be precluded from having access to the sought information if sought information is commingled with other information.

d. Cooperate with inspections, audits, investigations, and reviews.

3. Section 508 Annual Report

The contractor shall submit an annual Section 508 report in accordance with the schedule set forth by the Contracting Officer (CO)/Contracting Officer’s Representative (COR). The Section 508 Report Template and Instructions for completing the report are available at: http://www.hhs.gov/web/508/contracting/technology/vendors.html under "Vendor Information and Documents."

4. Multiple Principal Investigators Leadership Plan

The Contractor shall submit a revised/updated Leadership Plan in the event of a change in any of the Principal Investigators named in the Key Personnel Article in SECTION G of this contract. The revised plan is subject to review and approval by the Contracting Officer.

REPORTING REQUIREMENTS FOR USE WITH THE ELECTRONIC REPORT DELIVERABLE SUBMISSION (eRDS) SITE

All reports required herein shall be submitted in electronic format. All electronic contract deliverables shall be submitted via the NIAID electronic Report Deliverable Submission (eRDS) Site, available at the following website: https://erds.niaid.nih.gov/. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980
In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract.

The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer  
National Institutes of Health  
National Institute of Allergy and Infectious Diseases  
Office of Acquisitions  
5601 Fishers Lane  
Rockville, MD 20852

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed “Interagency Edison,” an electronic invention reporting system. Use of Interagency Edison is required as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.
SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

If special instructions regarding packaging, marking and shipping are required, these will be developed after receipt of proposals as a result of finalization of the Statement of Work during negotiations. Offerors will ship items in temperature controlled environment when necessary, shipments will be time sensitive/time critical and international shipping may apply.
SECTON E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, Contracting Officer’s Representative (COR) is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:
   National Institutes of Health
   National Institute of Allergy and Infectious Diseases
   Division of Allergy, Immunology and Transplantation
   5601 Fishers Lane
   Rockville, MD 20852

   Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

   FAR Clause 52.246-9, Inspection of Research and Development (Short Form) (April 1984).
SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

a. The period of performance of this contract shall be from 08/23/2019 through 08/22/2020.

b. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

<table>
<thead>
<tr>
<th>Option</th>
<th>Option Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option 1 Contract Year 2</td>
<td>08/23/2020 - 08/22/2021</td>
</tr>
<tr>
<td>Option 2 Contract Year 3</td>
<td>08/23/2021 - 08/22/2022</td>
</tr>
<tr>
<td>Option 3 Contract Year 4</td>
<td>08/23/2022 - 08/22/2023</td>
</tr>
<tr>
<td>Option 4 Contract Year 5</td>
<td>08/23/2023 - 08/22/2024</td>
</tr>
<tr>
<td>Option 5 Contract Year 6</td>
<td>08/23/2024 - 08/22/2025</td>
</tr>
<tr>
<td>Option 6 Contract Year 7</td>
<td>08/23/2025 - 08/22/2026</td>
</tr>
</tbody>
</table>

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Description Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

a. The items as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below [and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract]:

b. All electronic reports and deliverables shall be submitted through the NIAID Electronic Reports and Deliverables System, available here: https://erds.niaid.nih.gov/

ARTICLE F.3. LEVEL OF EFFORT

a. The Contractor shall have satisfied the requirement herein if not less than 5,200 nor more than 5,200 of the total direct labor Hours specified herein are furnished. These terms and conditions do not supersede the requirements of either the "Limitation of Cost" or "Limitation of Funds" clause.

b. In the event fewer Hours than the minimum specified number of direct labor Hours in the total categories are used by the Contractor in accomplishing the prescribed work and the Government has not invoked its rights under FAR Clause 52.249-6, TERMINATION (Cost-Reimbursement) incorporated in this contract, these parties agree that the fee will be adjusted based solely upon the quantity of Hours by which the number of direct labor Hours furnished is less than the number of direct labor Hours specified in this ARTICLE. The resulting adjustment shall be evidenced by a contract modification.

ARTICLE F.4. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: https://www.acquisition.gov/?q=browsefar.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:
52.242-15, Stop Work Order (August 1989)

Alternate I (April 1984) is applicable to this contract.
SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer’s Representative (COR) will represent the Government for the purpose of this contract:

TBD

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

[The alternate COR is responsible for carrying out the duties of the COR only in the event that the COR can no longer perform his/her duties as assigned.]

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract.

The Government may unilaterally change its COR designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.237-75 (December 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>TBD</td>
<td>TBD</td>
</tr>
</tbody>
</table>

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

a. Invoice Submission/Contract Financing Request and Contract Financial Reporting, NIH(RC)-4 for NIH Cost-Reimbursement Type Contracts are attached and made part of this contract. The Contractor shall follow the
attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

   a. The original invoice shall be submitted to the following **designated billing office:**

      National Institutes of Health  
      Office of Financial Management  
      Commercial Accounts  
      2115 East Jefferson Street, Room 4B-432, MSC 8500  
      Bethesda, MD 20892-8500

   b. One copy of the invoice shall be submitted to the following **approving official:**

      Contracting Officer  
      Office of Acquisitions  
      National Institute of Allergy and Infectious Diseases  
      National Institutes of Health  
      5601 Fishers Lane  
      Rockville, MD 20852

      The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number. **[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]**

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

   a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Institute of Allergy and Infectious Diseases. .

   b. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor’s name on the face page of the contract. **[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]** If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

   c. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. **[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]** If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
d. Invoice Matching Option. This contract requires a two-way match.

e. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

f. The Contract Title is:

CIVICs Statistical, Data Management and Coordination Center (SDMCC)

g. Contract Line Items as follows:

<table>
<thead>
<tr>
<th>Line Item #</th>
<th>Line Item Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>TBD</td>
<td>TBD</td>
</tr>
</tbody>
</table>

b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6452.

c. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of the above referenced contract."

ARTICLE G.4. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)

a. Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

b. The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.

c. Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

(End of Clause)

ARTICLE G.5. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services  
Office of Acquisition Management and Policy  
National Institutes of Health  
6011 EXECUTIVE BLVD, ROOM 549C, MSC-7663  
BETHESDA MD 20892-7663
These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared Annually.

Interim and Final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address:

http://www.cpars.gov
SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.2. NIH POLICY ON ENHANCING REPRODUCIBILITY THROUGH RIGOR AND TRANSPARENCY

Contractors shall adhere to the NIH policy of enhancing reproducibility through rigor and transparency by addressing each of the four areas of the policy in performance of the Statement of Work and in publications, as applicable: 1) Scientific Premise; 2) Scientific Rigor; 3) Consideration of Relevant Biological Variables, including Sex; and 4) Authentication of Key Biological and/or Chemical Resources. This policy applies to all NIH funded research and development, from basic through advanced clinical studies. See NIH Guide Notice, NOT-OD-15-103, "Enhancing Reproducibility through Rigor and Transparency" and NOT-OD-15-102, "Consideration of Sex as a Biological Variable in NIH-funded Research" for more information. In addition, publications are expected to follow the guidance at http://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research, whether preclinical or otherwise, as appropriate. More information is available at http://grants.nih.gov/reproducibility/index.htm, including FAQs and a General Policy Overview.

ARTICLE H.3. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov. Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-071.html and http://publicaccess.nih.gov.

ARTICLE H.4. ACKNOWLEDGEMENT OF FEDERAL FUNDING

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.5. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.
ARTICLE H.6. MULTIPLE PRINCIPAL INVESTIGATORS

The NIH awarded this contract as a multiple Principal Investigators project. The Key Personnel Article in SECTION G of this contract designates the Contact Principal Investigator and all other Principal Investigators.

Contracts designating multiple Principal Investigators require a current Leadership Plan with updates as needed. The Contractor's Leadership Plan, dated TBD, (and as modified thereafter, in accordance with the Reporting Requirements Article in SECTION C of this contract), is hereby incorporated by reference.

ARTICLE H.7. PRIVACY ACT, HHSAR 352.224-70 (December 2015)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations.

The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)).

The Contractor shall ensure that each of its employees knows the prescribed rules of conduct in CFR 45 part 5b and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records [5 U.S.C. 552a(m)(1)]. The contract work statement:

(a) identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and

(b) specifies the disposition to be made of such records upon completion of contract performance.

ARTICLE H.8. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

ARTICLE H.9. GUN CONTROL

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

ARTICLE H.10. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-7, Option for Increased Quantity-Separately Priced Line Item set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost [plus fixed fee] of the contract will be increased as set forth in the ESTIMATED COST [PLUS FIXED FEE].

ARTICLE H.11. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

1. The Small Business Subcontracting Plan, dated TBD is attached hereto and made a part of this contract.
2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at [http://www.esrs.gov](http://www.esrs.gov).

1. Individual Subcontract Reports (ISR)

   Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:
   
   April 30th  
   October 30th  
   Expiration Date of Contract

2. Summary Subcontract Report (SSR)

   Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

   October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address:

TBD  
Contracting Officer

ARTICLE H.12. HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS

ARTICLE H.12.1. INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY

A. Baseline Security Requirements

1. **Applicability**- The requirements herein apply whether the entire contract or order (hereafter "contract"), or portion thereof, includes either or both of the following:

   a. Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) employee will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.

   b. Operate a Federal System Containing Information: A Contractor (and/or any subcontractor) will operate a federal system and information technology containing data that supports the HHS mission. In addition to the Federal Acquisition Regulation (FAR) Subpart 2.1 definition of "information technology" (IT), the term as used in this section includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources.
2. **Safeguarding Information and Information Systems** - In accordance with the Federal Information Processing Standards Publication (FIPS) 199, Standards for Security Categorization of Federal Information and Information Systems, the Contractor (and/or any subcontractor) shall:

a. Protect government information and information systems in order to ensure:

   - **Confidentiality**, which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;
   - **Integrity**, which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and
   - **Availability**, which means ensuring timely and reliable access to and use of information.

b. Provide security for any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor on behalf of HHS regardless of location. In addition, if new or unanticipated threats or hazards are discovered by either the agency or contractor, or if existing safeguards have ceased to function, the discoverer shall immediately, **within one (1) hour or less**, bring the situation to the attention of the other party.

c. Adopt and implement the policies, procedures, controls, and standards required by the HHS Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain the HHS Information Security Program security requirements, outlined in the HHS Information Security and Privacy Policy (IS2P), by contacting the CO/COR or emailing fisma@hhs.gov.

d. Comply with the Privacy Act requirements.

3. **Information Security Categorization** - In accordance with FIPS 199 and National Institute of Standards and Technology (NIST) Special Publication (SP) 800-60, Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories, Contractor Non-Disclosure Agreement and based on information provided by the ISSO, CISO, or other security representative, the risk level for each Security Objective and the Overall Risk Level, which is the highest watermark of the three factors (Confidentiality, Integrity, and Availability) of the information or information system are the following:

   - **Confidentiality**: [X] Low [ ] Moderate [ ] High
   - **Integrity**: [ ] Low [X] Moderate [ ] High
   - **Availability**: [X] Low [ ] Moderate [ ] High
   - **Overall Risk Level**: [ ] Low [X] Moderate [ ] High

Based on information provided by the ISSO, Privacy Office, system/data owner, or other security or privacy representative, it has been determined that this solicitation/contract involves:

   [X] No PII [ ] Yes PII

**Personally Identifiable Information (PII).** Per the Office of Management and Budget (OMB) Circular A-130, "PII is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual." Examples of PII include, but are not limited to the following: social security number, date and place of birth, mother's maiden name, biometric records, etc.

PII Confidentiality Impact Level has been determined to be: [X] Low [ ] Moderate [ ] High
4. **Controlled Unclassified Information (CUI)**- CUI is defined as "information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information." The Contractor (and/or any subcontractor) must comply with Executive Order 13556, Controlled Unclassified Information, (implemented at 3 CFR, part 2002) when handling CUI. 32 C.F.R. 2002.4(aa) As implemented the term "handling" refers to "...any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing of the information." 81 Fed. Reg. 63323. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, shall be:

   a. Marked appropriately;
   b. Disclosed to authorized personnel on a Need-To-Know basis;
   c. Protected in accordance with NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline if handled by a Contractor system operated on behalf of the agency, or NIST SP 800-171, Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations if handled by internal Contractor system; and
   d. Returned to HHS control, destroyed when no longer needed, or held until otherwise directed. Destruction of information and/or data shall be accomplished in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

5. **Protection of Sensitive Information**- For security purposes, information is or may be sensitive because it requires security to protect its confidentiality, integrity, and/or availability. The Contractor (and/or any subcontractor) shall protect all government information that is or may be sensitive in accordance with OMB Memorandum M-06-16, Protection of Sensitive Agency Information by securing it with a FIPS 140-2 validated solution.

6. **Confidentiality and Nondisclosure of Information**- Any information provided to the contractor (and/or any subcontractor) by HHS or collected by the contractor on behalf of HHS shall be used only for the purpose of carrying out the provisions of this contract and shall not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and shall ensure that all work performed by its employees and subcontractors shall be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any HHS records may be made available or disclosed shall be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein.

The confidentiality, integrity, and availability of such information shall be protected in accordance with HHS and NIH policies. Unauthorized disclosure of information will be subject to the HHS/NIH sanction policies and/or governed by the following laws and regulations:

   a. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);
   b. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and

Each employee, including subcontractors, having access to non-public Department information under this acquisition shall complete the "Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: [https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf](https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf). A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer/COR prior to performing any work under this acquisition.

8. **Government Websites** - All new and existing public-facing government websites must be securely configured with Hypertext Transfer Protocol Secure (HTTPS) using the most recent version of Transport Layer Security (TLS). In addition, HTTPS shall enable HTTP Strict Transport Security (HSTS) to instruct compliant browsers to assume HTTPS at all times to reduce the number of insecure redirects and protect against attacks that attempt to downgrade connections to plain HTTP. For internal-facing websites, the HTTPS is not required, but it is highly recommended.

9. **Contract Documentation** - The Contractor shall use provided templates, policies, forms and other agency documents provided by the Contracting Officer and the Contracting Officer's Representative to comply with contract deliverables as appropriate.

10. **Standard for Encryption** - The Contractor (and/or any subcontractor) shall:

    a. Comply with the HHS Standard for Encryption of Computing Devices and Information to prevent unauthorized access to government information.
    
    b. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with FIPS 140-2 validated encryption solution.
    
    c. Secure all devices (i.e., desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices meet HHS and NIH-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).
    
    d. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative within 15 days of the validation.
    
    e. Use the Key Management system on the HHS personal identification verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys. Encryption keys shall be provided to the COR upon request and at the conclusion of the contract.

11. **Contractor Non-Disclosure Agreement (NDA)** - Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract shall complete the NIH non-disclosure agreement [https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf](https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf), as applicable. A copy of each signed and witnessed NDA shall be submitted to the Contracting Officer (CO) and/or CO Representative (COR) prior to performing any work under this acquisition.

12. **Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA)** - The Contractor shall assist the NIH Office of the Senior Official for Privacy (SOP) or designee with conducting a PTA for the information system and/or information handled under this contract to determine whether or not a full PIA needs to be completed. The NIH PIA guide is located at [https://oma.od.nih.gov/forms/Privacy%20Documents/Documents/NIH%20PIA%20Guide.pdf](https://oma.od.nih.gov/forms/Privacy%20Documents/Documents/NIH%20PIA%20Guide.pdf).

    a. If the results of the PTA show that a full PIA is needed, the Contractor shall assist the OpDiv SOP or designee with completing a PIA for the system or information within 60 days after completion of the PTA and in accordance with HHS policy and OMB M-03-22, Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.
    
    b. The Contractor shall assist the NIH Office of the SOP or designee in reviewing the PIA at least every three years throughout the system development lifecycle (SDLC)/information lifecycle, or when determined by the agency
that a review is required based on a major change to the system, or when new types of PII are collected that introduces new or increased privacy risks, whichever comes first.

B. TRAINING

1. Mandatory Training for All Contractor Staff- All Contractor (and/or any subcontractor) employees assigned to work on this contract shall complete the applicable HHS/NIH Contractor Information Security Awareness, Privacy, and Records Management training course at [http://irtsectraining.nih.gov/](http://irtsectraining.nih.gov/) before performing any work under this contract. Thereafter, the employees shall complete NIH Information Security Awareness, Privacy, and Records Management training at least annually, during the life of this contract. All provided training shall be compliant with HHS training policies.

2. Role-based Training- All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role-based training annually commensurate with their role and responsibilities in accordance with HHS policy and the HHS Role-Based Training (RBT) of Personnel with Significant Security Responsibilities Memorandum. Read further guidance about the NIH Role-based Training [https://ocio.nih.gov/aboutus/publicinfosecurity/securitytraining/Pages/rolebasedtraining.aspx](https://ocio.nih.gov/aboutus/publicinfosecurity/securitytraining/Pages/rolebasedtraining.aspx)

3. Training Records- The Contractor (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS policy. A copy of the training records shall be provided to the CO and/or COR within 30 days after contract award and annually thereafter or upon request.

C. RULES OF BEHAVIOR

1. The Contractor (and/or any subcontractor) shall ensure that all employees performing on the contract comply with the HHS Information Technology General Rules of Behavior, and comply with the NIH Information Technology General Rules of Behavior [https://ocio.nih.gov/InfoSecurity/training/Pages/nihitrob.aspx](https://ocio.nih.gov/InfoSecurity/training/Pages/nihitrob.aspx), which are contained in the NIH Information Security Awareness Training Course [http://irtsectraining.nih.gov](http://irtsectraining.nih.gov)

2. All Contractor employees performing on the contract must read and adhere to the Rules of Behavior before accessing Department data or other information, systems, and/or networks that store/process government information, initially at the beginning of the contract and at least annually thereafter, which may be done as part of annual NIH Information Security Awareness Training. If the training is provided by the contractor, the signed Rules of Behavior must be provided as a separate deliverable to the CO and/or COR per defined timelines above.

D. INCIDENT RESPONSE

The Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/NIH IRT teams within 24 hours, whether the response is positive or negative.

FISMA defines an incident as “an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies.. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines incidents as events involving cyber
security and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.

A privacy breach is a type of incident and is defined by Federal Information Security Modernization Act (FISMA) as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines a breach as "a suspected or confirmed incident involving PII".

In the event of a suspected or confirmed incident or breach, the Contractor (and/or any subcontractor) shall:

1. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract so as to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.

2. NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, the Contractor shall send NIH approved notifications to affected individuals in accordance with https://ocio.nih.gov/InfoSecurity/IncidentResponse/Pages/ir_guidelines.aspx

3. Report all suspected and confirmed information security and privacy incidents and breaches to the NIH Incident Response Team (IRT) via email at IRT@mail.nih.gov, COR, CO, the NIH Office of the SOP (or his or her designee), and other stakeholders, including incidents involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour, and consistent with the applicable NIH and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contract information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor shall:

   a. cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;

   b. not include any sensitive information in the subject or body of any reporting e-mail; and

   c. encrypt sensitive information in attachments to email, media, etc.

4. Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information HHS and NIH incident response policies when handling PII breaches.

5. Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to contractor facilities during a breach/incident investigation within an hour of discovery.

E. POSITION SENSITIVITY DESIGNATIONS
All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR). The following position sensitivity designation levels apply to this solicitation/contract:

[ ] Level 6: Public Trust - High Risk. Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

[X] Level 5: Public Trust - Moderate Risk. Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[ ] Level 1: Non-Sensitive. Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

F. HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12

The Contractor (and/or any subcontractor) and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; OMB M-05-24; FIPS 201, Personal Identity Verification (PIV) of Federal Employees and Contractors; HHS HSPD-12 policy; and Executive Order 13467, Part 1 §1.2.

For additional information, see HSPD-12 policy at: https://www.dhs.gov/homeland-security-presidential-directive-12

Roster-

a. The Contractor (and/or any subcontractor) shall submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster shall be submitted to the COR and/or CO within fourteen (14) calendar days after the effective date of this contract. Any revisions to the roster as a result of staffing changes shall be submitted within seven (7) calendar days of the change. The COR will notify the Contractor of the appropriate level of investigation required for each staff member. An electronic template, “Roster of Employees Requiring Suitability Investigations,” is available for contractor use at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx.

b. If the Contractor is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate suitability level. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

c. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

d. The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

e. All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract. Contractors may begin work after the fingerprint check has been completed.

f. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR
clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.

g. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more that the cost of the additional investigation(s).

h. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

i. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.

j. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

G. CONTRACT INITIATION AND EXPIRATION

1. General Security Requirements- The Contractor (and/or any subcontractor) shall comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the contractor shall follow the HHS EPLC framework and methodology or and in accordance with the HHS Contract Closeout Guide (2012).

HHS EA requirements may be located here: https://www.hhs.gov/ocio/ea/documents/proplans.html

2. System Documentation- Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-64, Security Considerations in the System Development Life Cycle, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.

3. Sanitization of Government Files and Information- As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) shall provide all required documentation in accordance with the NIH Media Sanitization and Disposal Policy to the CO and/or COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

4. Notification- The Contractor (and/or any subcontractor) shall notify the CO and/or COR and system ISSO within fifteen days before an employee stops working under this contract.

5. Contractor Responsibilities Upon Physical Completion of the Contract- The contractor (and/or any subcontractors) shall return all government information and IT resources (i.e., government information in non-government-owned systems, media, and backup systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor shall provide a certification that all government information has been properly sanitized and purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and/or NIH policies.

6. The Contractor (and/or any subcontractor) shall perform and document the actions identified in the NIH Contractor Employee Separation Checklist https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf when an employee terminates work under this contract within 2 days of
the employee's exit from the contract. All documentation shall be made available to the CO and/or COR upon request.

H. RECORDS MANAGEMENT AND RETENTION

The Contractor (and/or any subcontractor) shall maintain all information in accordance with Executive Order 13556 -- Controlled Unclassified Information, National Archives and Records Administration (NARA) records retention policies and schedules and HHS/NIH policies and shall not dispose of any records unless authorized by HHS/NIH. In the event that a contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, it shall be documented and reported as an incident in accordance with HHS/NIH policies.

ARTICLE H.12.2. PRIVACY ACT

It has been determined that this contract is subject to the Privacy Act of 1974, because this contract provides for the design, development, or operation of a system of records on individuals.

The System of Records Notice (SORN) that is applicable to this contract is: 09-25-0200.

The design, development, or operation work the Contractor is to perform is: a system of records on individuals.

The Contractor and any Subcontractor must follow disposition to be made of the Privacy Act records upon completion of contract performance shall be in accordance with Section C of the contract, and by direction of the Contracting Officer/Contracting Officer's representative.

ARTICLE H.13. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY NOTICE

HHSAR 352.239-73 (December 2015)

a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.


c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility. In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document--in detail--whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site http://www.hhs.gov/web/508 . In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.
d. Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

The "HHS Section 508 Product Assessment Template" is included in SECTION J - List of Attachments, of this solicitation.

ARTICLE H.14. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SId=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45

As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;

2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and

2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any NIH-funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.
c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the NIH-funded research.

d. Require that each Investigator who is planning to participate in the NIH-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for NIH-funded research. Require that each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to NIH-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to NIH-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: Could be affected by the NIH-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Offerors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the NIH-funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the NIH-funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will
bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that NIH-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

ARTICLE H.15. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause 352.227-70, Publications and Publicity incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute of Allergy & Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. TBD"

a. Advanced Copies of Press Releases

Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The contractor shall ensure that the Contracting Officer's Representative (COR) has received an advance copy of any press release related to this contract not less than four (4) working days prior to the issuance of the press release.

ARTICLE H.16. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services
Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.17. SHARING RESEARCH DATA

[The data sharing plan submitted by the Contractor is acceptable/The Contractor's data sharing plan, dated TBD is hereby incorporated by reference.] The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

https://grants.nih.gov/policy/sharing.htm

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in
NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

**ARTICLE H.18. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)**

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: [http://apps.usfa.fema.gov/hotel/](http://apps.usfa.fema.gov/hotel/).

**ARTICLE H.19. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES**

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

**ARTICLE H.20. USE OF FUNDS FOR CONFERENCES, MEETINGS AND FOOD**

The Contractor shall not use contract funds (direct or indirect) to conduct meetings or conferences in performance of this contract without prior written Contracting Officer approval.

In addition, the use of contract funds to purchase food for meals, light refreshments, or beverages is expressly prohibited.
PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING ARTICLE I.1. GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

The complete listing of these clauses may be accessed at: https://oamp.od.nih.gov/DGS/reference-material-prospective-offerors-and-contractors

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT
ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

a. Alternate II (August 2016) of FAR Clause 52.215-2, Audit and Records--Negotiation (October 2010) is added.

b. FAR Clause 52.215-23, Limitations on Pass-Through Charges (October 2009), is added.

c. Alternate IV (October 2010) of FAR Clause 52.215-21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data--Modifications (October 2010) is added.

d. FAR Clauses 52.219-9, Small Business Subcontracting Plan (November 2016), and 52.219-16, Liquidated Damages--Subcontracting Plan (January 1999) are deleted in their entirety.
ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause 52.203-13, Contractor Code of Business Ethics and Conduct (October 2015).

2. FAR Clause 52.203-14, Display of Hotline Poster(s) (October 2015).
   “.....(3) Any required posters may be obtained as follows:

<table>
<thead>
<tr>
<th>Poster(s)</th>
<th>Obtain From</th>
</tr>
</thead>
</table>

3. FAR Clause 52.204-9, Personal Identity Verification of Contractor Personnel (January 2011).

4. FAR Clause 52.209-10, Prohibition on Contracting With Inverted Domestic Corporations (November 2015).

5. FAR Clause 52.210-1, Market Research (April 2011).


7. FAR Clause 52.217-7, Option for Increased Quantity - Separately Priced Line Item (March 1989).
   “....The Contracting Officer may exercise the option by written notice to the Contractor within 60 days...”

8. FAR Clause 52.219-6, Notice of Total Small Business Set-Aside (November 2011).
   Alternate I (November 2011) is not applicable to this contract.
   Alternate II (November 2011) is not applicable to this contract.

9. FAR Clause 52.219-14, Limitations on Subcontracting (November 2011).

10. FAR Clause 52.219-28, Post-Award Small Business Program Rerepresentation (July 2013).

11. FAR Clause 52.224-1, Privacy Act Notification (April 1984).
12. FAR Clause 52.224-2, Privacy Act (April 1984).

13. FAR Clause 52.227-14, Rights in Data - General (May 2014).

14. FAR Clause 52.227-16, Additional Data Requirements (June 1987).

15. FAR Clause 52.227-17, Rights in Data--Special Works (December 2007).

16. FAR Clause 52.242-3, Penalties for Unallowable Costs (May 2014).

17. FAR Clause 52.247-63, Preference for U.S. Flag Air Carriers (June 2003).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

1. HHSAR Clause 352.211-2, Conference Sponsorship Request and Conference Materials Disclaimer (December 2015)

2. HHSAR Clause 352.211-3, Paperwork Reduction Act (December 2015)

3. HHSAR Clause 352.231-70, Salary Rate Limitation (December 2015)

   Note: The Salary Rate Limitation is at the Executive Level II Rate.

   See the following website for Executive Schedule rates of pay: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/.

   (For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)
ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause 52.204-21, **Basic Safeguarding of Covered Contractor Information Systems** (June 2016)

   a. Definitions. As used in this clause--

   "Covered contractor information system" means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

   "Federal contract information" means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public Web sites) or simple transactional information, such as necessary to process payments.

   "Information" means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

   "Information system" means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

   "Safeguarding" means measures or controls that are prescribed to protect information systems.

   b. Safeguarding requirements and procedures.

   1. The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

   i. Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

   ii. Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

   iii. Verify and control/limit connections to and use of external information systems.

   iv. Control information posted or processed on publicly accessible information systems.

   v. Identify information system users, processes acting on behalf of users, or devices.

   vi. Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

   vii. Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.
viii. Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

ix. Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

x. Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

xi. Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

xii. Identify, report, and correct information and information system flaws in a timely manner.

xiii. Provide protection from malicious code at appropriate locations within organizational information systems.

xiv. Update malicious code protection mechanisms when new releases are available.

xv. Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

2. Other requirements. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

c. Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

2. FAR Clause 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (July 2013)

As prescribed in 9.104-7(c), insert the following clause:

a. The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the System for Award Management (SAM) database at http://www.acquisition.gov.

b. As required by section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111-212), all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIIS consists of two segments--

1. The non-public segment, into which Government officials and the Contractor post information, which can only be viewed by--

   i. Government personnel and authorized users performing business on behalf of the Government; or
ii. The Contractor, when viewing data on itself; and

2. The publicly-available segment, to which all data in the non-public segment of FAPIIS is automatically transferred after a waiting period of 14 calendar days, except for--
   i. Past performance reviews required by subpart 42.15;
   ii. Information that was entered prior to April 15, 2011; or
   iii. Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.

c. The Contractor will receive notification when the Government posts new information to the Contractor's record.

1. If the Contractor asserts in writing within 7 calendar days, to the Government official who posted the information, that some of the information posted to the non-public segment of FAPIIS is covered by a disclosure exemption under the Freedom of Information Act, the Government official who posted the information must within 7 calendar days remove the posting from FAPIIS and resolve the issue in accordance with agency Freedom of Information procedures, prior to reposting the releasable information. The contractor must cite 52.209-9 and request removal within 7 calendar days of the posting to FAPIIS.

2. The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.

3. As required by section 3010 of Pub. L. 111-212, all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available.

d. Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.

(End of clause)
## PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

### SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

### SOLICITATION ATTACHMENTS

<table>
<thead>
<tr>
<th>Attachment No.</th>
<th>Title</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attachment 1:</td>
<td>Packaging and Delivery of Proposals for Use with the NIH electronic Contract Proposal Submission (eCPS) Website</td>
<td>See Attachment Section at the end of this RFP.</td>
</tr>
<tr>
<td>Attachment 2:</td>
<td>Proposal Intent Response Sheet</td>
<td>See Attachment Section at the end of this RFP.</td>
</tr>
<tr>
<td>Attachment 3:</td>
<td>Statement of Work</td>
<td>See Attachment Section at the end of this RFP.</td>
</tr>
<tr>
<td>Attachment 4:</td>
<td>Additional Technical Proposal Instructions</td>
<td>See Attachment Section at the end of this RFP.</td>
</tr>
<tr>
<td>Attachment 5:</td>
<td>Additional Business Proposal Instructions</td>
<td>See Attachment Section at the end of this RFP.</td>
</tr>
<tr>
<td>Attachment 6:</td>
<td>Reporting Requirements and Deliverables</td>
<td>See Attachment Section at the end of this RFP.</td>
</tr>
<tr>
<td>Attachment 7:</td>
<td>Section K - Representations, Certifications, and Other Statements of Offerors</td>
<td><a href="https://oamp.od.nih.gov/sites/default/files/dgs/contracting-forms/sectionk_508.pdf">https://oamp.od.nih.gov/sites/default/files/dgs/contracting-forms/sectionk_508.pdf</a></td>
</tr>
</tbody>
</table>

### TECHNICAL PROPOSAL ATTACHMENTS

<table>
<thead>
<tr>
<th>Attachment No.</th>
<th>Title</th>
<th>Location</th>
</tr>
</thead>
</table>

### BUSINESS PROPOSAL ATTACHMENTS

<table>
<thead>
<tr>
<th>Attachment No.</th>
<th>Title</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attachment No.</td>
<td>Title</td>
<td>Location</td>
</tr>
<tr>
<td>---------------</td>
<td>----------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Attachment 13:</td>
<td>Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet</td>
<td><a href="https://oamp.od.nih.gov/content/breakdown-proposed-estimated-cost-plus-fee-and-labor-hours">https://oamp.od.nih.gov/content/breakdown-proposed-estimated-cost-plus-fee-and-labor-hours</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td><a href="https://oamp.od.nih.gov/sites/default/files/DFASDocs/">https://oamp.od.nih.gov/sites/default/files/DFASDocs/</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td>buscntrctprpslsprdsht08-2014_508.xlsx</td>
</tr>
<tr>
<td></td>
<td>Form SF-LLL</td>
<td></td>
</tr>
</tbody>
</table>

**INFORMATIONAL ATTACHMENTS**

<table>
<thead>
<tr>
<th>Attachment No.</th>
<th>Title</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Form SF-LLL</td>
<td></td>
</tr>
</tbody>
</table>
PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST:

1. Go to the System for Award Management (SAM) and complete the Representations and Certifications. The SAM website may be accessed at: http://www.sam.gov; and

2. Complete, and INCLUDE as part of your BUSINESS PROPOSAL:
   SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS
   which is included as an Attachment in Section J-LIST OF ATTACHMENTS, SOLICITATION ATTACHMENTS of this solicitation.

If you are unable to access this SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

3. FAR Clause 52.204-19 Incorporation by Reference of Representations and Certifications (December 2014).

The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

(End of Clause)
SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2017)]

   a. Definitions. As used in this provision--

   "Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal. "In writing", "writing", or "written" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information. "Proposal modification" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award. "Proposal revision" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations. "Time," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

b. Amendments to solicitations. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

c. Submission, modification, revision, and withdrawal of proposals.

   1. Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

   2. The first page of the proposal must show--

      i. The solicitation number;

      ii. The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

      iii. A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

      iv. Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

      v. Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

3. Submission, modification, revision, and withdrawal of proposals.
(i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is “late” and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.
(d) Offer expiration date. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) Restriction on disclosure and use of data.

(1) The proposal submitted in response to this request may contain data (trade secrets; business data (e.g., commercial information, financial information, cost and pricing data); and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

"Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services (HHS), data contained in the portions of this proposal which the offeror has specifically identified by page number, paragraph, etc. as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that HHS may not be able to withhold a record (e.g. data, document, etc.) nor deny access to a record requested pursuant to the Act and that the HHS's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if HHS has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act. The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification)."

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

(f) Contract award.

(1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may
limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government’s best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

   (i) The agency’s evaluation of the significant weak or deficient factors in the debriefed offeror’s offer.

   (ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.

   (iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;

   (iv) A summary of the rationale for award.

   (v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

   (vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror’s initial proposal should contain the offeror’s best terms from a price and technical standpoint.
b. NOTICE OF SMALL BUSINESS SET-ASIDE

1. **General.** Offerors are solicited only from small business concerns. The procurement is to be awarded only to one or more such concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation’s full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive.

2. **Definitions.** The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the size standards in this solicitation. In addition to meeting these criteria, a small business concern submitting an offer in his own name shall furnish, in the performing the contract, only end items manufactured or produced by small business concerns in the United States or its outlying areas, provided that this additional requirement does not apply in connection with construction or service contracts.

c. TYPE OF CONTRACT AND NUMBER OF AWARDS

1. It is anticipated that one award will be made from this solicitation and that the award(s) will be made on/about August 23, 2019.

2. It is anticipated that the award(s) from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a term of one Base Year and six Option Periods, for a total of seven years.

3. FAR 16.301-3 limits use of any contract type, other than firm-fixed price, to a contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled, Adequate Accounting System in Section L.2. Business Proposal Instructions in this solicitation for additional information about this certification.

d. ESTIMATE OF EFFORT

In accordance with the Request for Proposal (RFP) design, the Government has issued a general announcement of the agency’s research interest. Submissions in response to this RFP will represent each offeror’s creative and innovative approach to the specific research. Therefore, the Government is unable to provide an estimate of effort but reminds all offerors that they shall propose effort that is consistent with the nature and complexity of their proposed research.

e. LEVEL OF EFFORT

The Government's requirement for the work set forth in the Statement of Work of this solicitation is 5,020 direct labor hours. It is estimated that the labor hours are constituted as specified below and will be expended approximately as follows:

<table>
<thead>
<tr>
<th>Labor Category</th>
<th>Labor Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional</td>
<td>3,120</td>
</tr>
<tr>
<td>Other Professional</td>
<td>1,040</td>
</tr>
<tr>
<td>Support</td>
<td>1,040</td>
</tr>
</tbody>
</table>

f. COMMITMENT OF PUBLIC FUNDS

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.
g. PROMOTING EFFICIENT SPENDING

On September 21, 2011, the Office of Management and Budget issued Memorandum M-11-35, entitled, "Eliminating Conference Spending and Promoting Efficiency in Government," emphasizing the President's priority to ensure that the Government operates with the utmost efficiency and eliminates unnecessary or wasteful spending. This was followed by the Executive Order on Delivering an Efficient, Effective, and Accountable Government (EO 13576) and the Executive Order on Promoting Efficient Spending (EO 13589). On January 3, 2012, the Department of Health and Human Services (DHHS) issued the memorandum “HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing, and Publications” (See http://www.hhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html).

In support of these directives, the NIH issued a January 30, 2012, Memorandum, entitled, "NIH Guidance Related to the HHS Policies on Promoting Efficient Spending: Use of Appropriated Funds for Conferences, Conference Grants and Meetings, Food, Promotional Items, and Printing and Publications." (See http://oamp.od.nih.gov/) Any contract awarded as a result of this solicitation will:

• Specifically prohibit the use of contract funds for the provision of food for meals, light refreshments and beverages for any NIH funded meeting or conference; and

• Limit the procurement of meeting space, promotional items, printing and publications.

h. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this SOLICITATIONS. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

i. RELEASE OF INFORMATION

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

j. PREPARATION COSTS

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

k. SERVICE OF PROTEST (SEPTEMBER 2006) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Office of Acquisitions
National Institute of Allergy and Infectious Diseases
National Institutes of Health
5601 Fishers Lane
Rockville, MD 20852

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.
2. **INSTRUCTIONS TO OFFERORS**

a. **GENERAL INSTRUCTIONS**

**INTRODUCTION**

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

1. **Contract Type and General Clauses**

   It is contemplated that a [cost-reimbursement [(completion/level of effort)/fixed price] type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

2. **Authorized Official and Submission of Proposal**

   The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper, printed/copied double-sided, on at least 30 percent post consumer fiber paper, as required by FAR 4.302(b), and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the SOLICITATION should be placed in the following order:

   I. COVER PAGE

      Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

   II. TECHNICAL PROPOSAL

      It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

   III. BUSINESS PROPOSAL

      It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

3. **Proposal Summary and Data Record (NIH-2043)**

   The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See SECTION J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

4. **Separation of Technical and Business Proposals**
The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

5. Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

6. Evaluation of Proposals

The Government will evaluate proposals in accordance with the factors set forth in PART IV, SECTION M of this RFP.

7. Potential Award Without Discussions

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

8. Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

**Hard Metric** - - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

**Soft Metric** - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

**Dual Systems** - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

9. Standards for Privacy of Individually Identifiable Health Information

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is
administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities") must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply.

Decisions about the applicability and implementation of the Privacy Rule reside with the Contractor and his/her institution. The OCR website (http://www.hhs.gov/ocr/) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

10. Privacy Act - Treatment of Proposal Information

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this SOLICITATION pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the Government Accountability Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

11. Selection of Offerors

a. The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation factors of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b. The business portion of each contract proposal found to be technical acceptable will be subjected to a cost and price analysis, management analysis, etc.
c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror’s past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d. If the Government intends to conduct discussions prior to awarding a contract -

1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain. Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

2. The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NIAID’s policy to conduct discussions with all offerors in the competitive range, NIAID reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR Part 315.

e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.

f. The NIAID reserves the right to make a single award, multiple awards, or no award at all to the SOLICITATION. In addition, the SOLICITATION may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

12. Institutional Responsibility Regarding Investigator Conflicts of Interest

45 CFR Part 94 promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under NIH contracts will be biased by any Investigator financial conflicts of interest. The Institution shall comply with all requirements of 45 CFR Part 94 at: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45.

13. Certification of Filing and Payment of Taxes

None of the funds appropriated or otherwise made available by the Consolidated Appropriations Act of FY 2014, may be used to enter into a contract in an amount greater than $5,000,000 unless the prospective contractor certifies in writing to the agency awarding the contract that, to the best of its knowledge and belief, the contractor has filed all Federal tax returns required during the 3 years preceding the certification, has not been convicted of a criminal offense under the Internal
Revenue Code of 1986, and has not, more than 90 days prior to certification, been notified of any unpaid Federal tax assessment for which the liability remains unsatisfied, unless the assessment is the subject of an installment agreement or offer in compromise that has been approved by the Internal Revenue Service and is not in default, or the assessment is the subject of a non-frivolous administrative or judicial proceeding.

14. Past Performance Information

a. Offerors shall submit the following information as part of their Business proposal.

A list of the last 5 contracts completed during the past Three years and THE LAST 3 CONTRACTS AWARDED] currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as any subcontract with a total value greater than $650,000.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

15. Prohibition on Contractor Involvement with Terrorist Activities

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.
16. HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS

16. HHS Security and Privacy Language for Information and Information Technology Procurements is applicable to this solicitation and the following information is provided to assist in proposal preparation.

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the ________ Technical/Business] Proposal entitled "Information Security."

The Homeland Security Presidential Directive (HSPD)-12 and the Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor (including subcontractor), or other source.

INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY

A. POSITION SENSITIVITY DESIGNATIONS

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR). The following position sensitivity designation levels apply to this solicitation/contract:

[ ] Level 6: Public Trust - High Risk. Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

[X] Level 5: Public Trust - Moderate Risk. Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[ ] Level 1: Non-Sensitive. Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

1. HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12

The Contractor (and/or any subcontractor) and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; OMB M-05-24; FIPS 201, Personal Identity Verification (PIV) of Federal Employees and Contractors; HHS HSPD-12 policy; and Executive Order 13467, Part 1 §1.2.

For additional information, see HSPD-12 policy at: https://www.dhs.gov/homeland-security-presidential-directive-12)

Roster-

a. The Contractor (and/or any subcontractor) shall submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster shall be submitted to the COR and/or CO within fourteen (14) calendar days after the effective date of this contract. Any revisions to the roster as a result of staffing changes shall be submitted within seven (7) calendar days of the change. The COR will notify the Contractor of the appropriate level of investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx.

- 57 -
b. If the Contractor is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate suitability level. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

c. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

d. The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

e. All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract. Contractors may begin work after the fingerprint check has been completed.

f. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.

g. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more that the cost of the additional investigation(s).

h. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

i. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.

j. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

B. Security Assessment and Authorization (SA&A) - A valid authority to operate (ATO) certifies that the Contractor's information system meets the contract's requirements to protect the agency data. If the system under this contract does not have a valid ATO, the Contractor (and/or any subcontractor) shall work with the agency and supply the deliverables required to complete the ATO within the specified timeline(s) within three (3) months after contract award. The Contractor shall conduct the SA&A requirements in accordance with HHS IS2P, NIST SP 800-37, Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach (latest revision).

For an existing ATO, Contracting Officer Representative must make a determination if the existing ATO provides appropriate safeguards or if an additional ATO is required for the performance of the contract and state as such. NIH acceptance of the ATO does not alleviate the Contractor's responsibility to ensure the system security and privacy controls are implemented and operating effectively.

C. SA&A Package Deliverables - The Contractor (and/or any subcontractor) shall provide an SA&A package within 30 days of contract award to the CO and/or COR. The following SA&A deliverables are required to complete the SA&A package.

- **System Security Plan (SSP)** - due within 30 days after contract award. The SSP shall comply with the NIST SP 800-18, Guide for Developing Security Plans for Federal Information Systems, the Federal Information Processing Standard (FIPS) 200, Recommended Security Controls for Federal Information Systems, and
NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline requirements, and other applicable NIST guidance as well as HHS and NIH policies and other guidance. The SSP shall be consistent with and detail the approach to IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The SSP shall provide an overview of the system environment and security requirements to protect the information system as well as describe all applicable security controls in place or planned for meeting those requirements. It should provide a structured process for planning adequate, cost-effective security protection for a system. The Contractor shall update the SSP at least annually thereafter.

- **Security Assessment Plan/Report (SAP/SAR)** - due 30 days after the contract award. The security assessment shall be conducted by the assessor and be consistent with NIST SP 800-53A, NIST SP 800-30, and HHS and NIH policies. The assessor will document the assessment results in the SAR.

The NIH should determine which security control baseline applies and then make a determination on the appropriateness/necessity of obtaining an independent assessment. Assessments of controls can be performed by contractor, government, or third parties, with third party verification considered the strongest. If independent assessment is required, include statement below. Thereafter, the Contractor, in coordination with the NIH shall conduct/assist in the assessment of the security controls and update the SAR at least annually.

- **Independent Assessment** - due 90 days after the contract award. The Contractor (and/or subcontractor) shall have an independent third-party validate the security and privacy controls in place for the system(s). The independent third party shall review and analyze the Security Authorization package, and report on technical, operational, and management level deficiencies as outlined in NIST SP 800-53. The Contractor shall address all "high" deficiencies before submitting the package to the Government for acceptance. All remaining deficiencies must be documented in a system Plan of Actions and Milestones (POA&M).

- **POA&M** - due 30 days after contract award. The POA&M shall be documented consistent with the HHS Standard for Plan of Action and Milestones and NIH policies. All high-risk weaknesses must be mitigated within 30 days and all medium weaknesses must be mitigated within 60 days from the date the weaknesses are formally identified and documented. The NIH will determine the risk rating of vulnerabilities. Identified risks stemming from deficiencies related to the security control baseline implementation, assessment, continuous monitoring, vulnerability scanning, and other security reviews and sources, as documented in the SAR, shall be documented and tracked by the Contractor for mitigation in the POA&M document. Depending on the severity of the risks, NIH may require designated POAM weaknesses to be remediated before an ATO is issued. Thereafter, the POA&M shall be updated at least quarterly.

D. **Contingency Plan and Contingency Plan Test** - due 60 days after contract award. The Contingency Plan must be developed in accordance with NIST SP 800-34, Contingency Planning Guide for Federal Information Systems, and be consistent with HHS and NIH policies. Upon acceptance by the System Owner, the Contractor, in coordination with the System Owner, shall test the Contingency Plan and prepare a Contingency Plan Test Report that includes the test results, lessons learned and any action items that need to be addressed. Thereafter, the Contractor shall update and test the Contingency Plan at least annually.

- **E-Authentication Questionnaire** - The contractor (and/or any subcontractor) shall collaborate with government personnel to ensure that an E-Authentication Threshold Analysis (E-auth TA) is completed to determine if a full E-Authentication Risk Assessment (E-auth RA) is necessary. System documentation developed for a system using E-auth TA/E-auth RA methods shall follow OMB 04-04 and NIST SP 800-63, Rev. 2, Electronic Authentication Guidelines. Based on the level of assurance determined by the E-Auth, the Contractor (and/or subcontractor) must ensure appropriate authentication to the system, including remote authentication, is in-place in accordance with the assurance level determined by the E-Auth (when required) in accordance with HHS policies.
E. Reporting and Continuous Monitoring

1. Following the initial ATOs, the Contractor (and/or any subcontractor) must perform the minimum ongoing continuous monitoring activities specified below, submit required deliverables by the specified due dates, and meet with the system/service owner and other relevant stakeholders to discuss the ongoing continuous monitoring activities, findings, and other relevant matters. The CSP will work with the agency to schedule ongoing continuous monitoring activities.

- **Information Security Continuous Monitoring** - Upon the government issuance of an Authority to Operate (ATO), the Contractor (and/or subcontractor)-owned/operated systems that input, store, process, output, and/or transmit government information, shall meet or exceed the information security continuous monitoring (ISCM) requirements in accordance with FISMA and NIST SP 800-137, Information Security Continuous Monitoring (ISCM) for Federal Information Systems and Organizations, and HHS IS2P. The following are the minimum requirements for ISCM:

  - **Annual Assessment/Pen Test** - Assess the system security and privacy controls (or ensure an assessment of the controls is conducted) at least annually to determine the implemented security and privacy controls are operating as intended and producing the desired results (this may involve penetration testing conducted by the agency or independent third-party. In addition, review all relevant SA&A documentation (SSP, POA&M, Contingency Plan, etc.) and provide updates by specified due date provided by the Contracting Officer's Representative.

  - **Asset Management** - Using any available Security Content Automation Protocol (SCAP)-compliant automated tools for active/passive scans, provide an inventory of all information technology (IT) assets for hardware and software, (computers, servers, routers, databases, operating systems, etc.) that are processing HHS-owned information/data. It is anticipated that this inventory information will be required to be produced at least 60 days after contract award. IT asset inventory information shall include IP address, machine name, operating system level, security patch level, and SCAP-compliant format information. The contractor shall maintain a capability to provide an inventory of 100% of its IT assets using SCAP-compliant automated tools.

  - **Configuration Management** - Use available SCAP-compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and process government information. Compliance will be measured using IT assets and standard HHS and government configuration baselines at least within 60 days. The contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP-compliant automated tools.

  - **Vulnerability Management** - Use SCAP-compliant automated tools for authenticated scans to scan information system(s) and detect any security vulnerabilities in all assets (computers, servers, routers, Web applications, databases, operating systems, etc.) that store and process government information. Contractors shall actively manage system vulnerabilities using automated tools and technologies where practicable and in accordance with HHS policy. Automated tools shall be compliant with NIST-specified SCAP standards for vulnerability identification and management. The contractor shall maintain a capability to provide security vulnerability scanning information for 100% of IT assets using SCAP-compliant automated tools and report to the agency at least within 30 days of the contract award.

  - **Patching and Vulnerability Remediation** - Install vendor released security patches and remediate critical and high vulnerabilities in systems processing government information in an expedited manner, within vendor and agency specified timeframes.

  - **Secure Coding** - Follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.
• **Boundary Protection** - The contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities is routed through a Trusted Internet Connection (TIC).

• A security control assessment must be conducted by a FedRAMP third-party assessment organization (3PAO) for the initial ATO and annually thereafter or whenever there is a significant change to the system's security posture in accordance with the FedRAMP Continuous Monitoring Plan.

2. At a minimum, the Contractor must provide the following artifacts/deliverables on a monthly basis as directed by the Contracting Officer/Contracting Officer's Representative.

   a. Operating system, database, Web application, and network vulnerability scan results;
   b. Updated POA&Ms;
   c. Any updated authorization package documentation as required by the annual attestation/assessment/review or as requested by the NIH System Owner or AO; and
   d. Any configuration changes to the system and/or system components or CSP's cloud environment, that may impact HHS/NIH's security posture. Changes to the configuration of the system, its components, or environment that may impact the security posture of the system under this contract must be approved by the agency.

F. **Configuration Baseline**

1. The contractor shall certify that applications are fully functional and operate correctly as intended on systems using the US Government Configuration Baseline (USGCB), DISA Security Technical Implementation Guides (STIGs), Center for Information Security (CIS) Security Benchmarks or any other HHS-identified configuration baseline. The standard installation, operation, maintenance, updates, and/or patching of software shall not alter the configuration settings from the approved HHS/NIH.

   • The Contractor shall configure its computers that contain HHS data with the latest applicable United States Government Configuration Baseline (USGCB) and/or other approved HHS IT Security Configurations. (See: [https://usgcb.nist.gov/](https://usgcb.nist.gov/)). Note: Approved security configurations include, but are not limited to, those published by the Department, the NIH, and the National Institute of Standards and Technology (NIST). NIH may have security configurations that are more stringent than the minimum baseline set by the Department or NIST. When incorporating such security configuration requirements in solicitations and contracts, the NIH CISO and/or Information System Security Officer (ISSO) shall be consulted to determine the appropriate configuration reference for a particular system or services acquisition.

   • The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS and must adhere to all NIH configuration standards and policies (See: [https://ocio.nih.gov/InfoSecurity/Policy/Pages/CM.aspx](https://ocio.nih.gov/InfoSecurity/Policy/Pages/CM.aspx).

   • The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.
• The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.

• The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (See: http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf ), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.

• The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

2. The contractor shall use Security Content Automation Protocol (SCAP) validated tools with configuration baseline scanner capability to certify their products operate correctly with HHS and NIST defined configurations and do not alter these settings.

G. **Standard for Encryption**- The Contractor (and/or any subcontractor) shall:

a. Comply with the HHS Standard for Encryption of Computing Devices and Information to prevent unauthorized access to government information.

b. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with FIPS 140-2 validated encryption solution.

c. Secure all devices (i.e.: desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices meet HHS and NIH-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).

d. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer’s Technical Representative within 15 days of the validation.

e. Use the Key Management system on the HHS personal identification verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys. Encryption keys shall be provided to the COR upon request and at the conclusion of the contract.

H. **Applicability**- The requirements herein apply whether the entire contract or order (hereafter "contract"), or portion thereof, includes either or both of the following:

a. Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) employee will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.

b. Operate a Federal System Containing Information: A Contractor (and/or any subcontractor) will operate a federal system and information technology containing data that supports the HHS mission. In addition to the Federal Acquisition Regulation (FAR) Subpart 2.1 definition of “information technology” (IT), the term as used in this section includes computers, ancillary
equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources.

I. Safeguarding Information and Information Systems- In accordance with the Federal Information Processing Standards Publication (FIPS)199, Standards for Security Categorization of Federal Information and Information Systems, the Contractor (and/or any subcontractor) shall:

   a. Protect government information and information systems in order to ensure:

      • **Confidentiality**, which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;

      • **Integrity**, which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and

      • **Availability**, which means ensuring timely and reliable access to and use of information.

   b. Provide security for any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor on behalf of HHS regardless of location. In addition, if new or unanticipated threats or hazards are discovered by either the agency or contractor, or if existing safeguards have ceased to function, the discoverer shall immediately, within one (1) hour or less, bring the situation to the attention of the other party.

   c. Adopt and implement the policies, procedures, controls, and standards required by the HHS Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain the HHS Information Security Program security requirements, outlined in the HHS Information Security and Privacy Policy (IS2P), by contacting the CO/COR or emailing fisma@hhs.gov.

   d. Comply with the Privacy Act requirements.

J. Information Security Categorization- In accordance with FIPS 199 and National Institute of Standards and Technology (NIST) Special Publication (SP) 800-60, Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories, Contractor Non-Disclosure Agreement and based on information provided by the ISSO, CISO, or other security representative, the risk level for each Security Objective and the Overall Risk Level, which is the highest watermark of the three factors (Confidentiality, Integrity, and Availability) of the information or information system are the following:

   Confidentiality: [X] Low [ ] Moderate [ ] High

   Integrity: [ ] Low [X] Moderate [ ] High

   Availability: [X] Low [ ] Moderate [ ] High

   Overall Risk Level: [ ] Low [X] Moderate [ ] High

Based on information provided by the ISSO, Privacy Office, system/data owner, or other security or privacy representative, it has been determined that this solicitation/contract involves:

[X] No PII [ ] Yes PII
Personally Identifiable Information (PII). Per the Office of Management and Budget (OMB) Circular A-130, "PII is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual." Examples of PII include, but are not limited to the following: social security number, date and place of birth, mother’s maiden name, biometric records, etc.

PII Confidentiality Impact Level has been determined to be: [X] Low [ ] Moderate [ ] High

K. CONTRACT INITIATION AND EXPIRATION

1. General Security Requirements- The Contractor (and/or any subcontractor) shall comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the contractor shall follow the HHS EPLC framework and methodology or in accordance with the HHS Contract Closeout Guide (2012). HHS EA requirements may be located here: https://www.hhs.gov/ocio/ea/documents/proplans.html

2. System Documentation- Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-64, Security Considerations in the System Development Life Cycle, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.

3. Sanitization of Government Files and Information- As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) shall provide all required documentation in accordance with the NIH Media Sanitization and Disposal Policy to the CO and/or COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

4. Notification- The Contractor (and/or any subcontractor) shall notify the CO and/or COR and system ISSO within fifteen days before an employee stops working under this contract.

5. Contractor Responsibilities Upon Physical Completion of the Contract- The contractor (and/or any subcontractors) shall return all government information and IT resources (i.e., government information in non-government-owned systems, media, and backup systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor shall provide a certification that all government information has been properly sanitized and purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and/or NIH policies.

6. The Contractor (and/or any subcontractor) shall perform and document the actions identified in the NIH Contractor Employee Separation Checklist https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf when an employee terminates work under this contract within 2 days of the employee's exit from the contract. All documentation shall be made available to the CO and/or COR upon request.

L. TRAINING

1. Mandatory Training for All Contractor Staff- All Contractor (and/or any subcontractor) employees assigned to work on this contract shall complete the applicable HHS/NIH Contractor Information Security Awareness, Privacy, and Records Management training course at http://irtsectraining.nih.gov/ before performing any work under this contract. Thereafter, the employees shall complete NIH Information Security Awareness, Privacy, and Records Management training at least annually, during the life of this contract. All provided training shall be compliant with HHS training policies.
2. **Role-based Training** - All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role-based training annually commensurate with their role and responsibilities in accordance with HHS policy and the HHS Role-Based Training (RBT) of Personnel with Significant Security Responsibilities Memorandum. Read further guidance about the NIH Role-based Training [https://ocio.nih.gov/aboutus/publicinfosecurity/securitytraining/Pages/rolebasedtraining.aspx](https://ocio.nih.gov/aboutus/publicinfosecurity/securitytraining/Pages/rolebasedtraining.aspx)

3. **Training Records** - The Contractor (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS policy. A copy of the training records shall be provided to the CO and/or COR within 30 days after contract award and annually thereafter or upon request.

M. **RULES OF BEHAVIOR**

1. The Contractor (and/or any subcontractor) shall ensure that all employees performing on the contract comply with the HHS Information Technology General Rules of Behavior, and comply with the NIH Information Technology General Rules of Behavior [https://ocio.nih.gov/InfoSecurity/training/Pages/nihitrob.aspx](https://ocio.nih.gov/InfoSecurity/training/Pages/nihitrob.aspx), which are contained in the NIH Information Security Awareness Training Course [http://irtsectraining.nih.gov](http://irtsectraining.nih.gov)

2. All Contractor employees performing on the contract must read and adhere to the Rules of Behavior before accessing Department data or other information, systems, and/or networks that store/process government information, initially at the beginning of the contract and at least annually thereafter, which may be done as part of annual NIH Information Security Awareness Training. If the training is provided by the contractor, the signed Rules of Behavior must be provided as a separate deliverable to the CO and/or COR per defined timelines above.

N. **INCIDENT RESPONSE**

The Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/NIH IRT teams within 24 hours, whether the response is positive or negative.

FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines incidents as events involving cyber security and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.

A privacy breach is a type of incident and is defined by Federal Information Security Modernization Act (FISMA) as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines a breach as "a suspected or confirmed incident involving PII".

1. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract so as to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.

2. NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, the Contractor shall send NIH approved notifications
to affected individuals in accordance with https://ocio.nih.gov/InfoSecurity/IncidentResponse/Pages/ir_guidelines.aspx

3. Report all suspected and confirmed information security and privacy incidents and breaches to the NIH Incident Response Team (IRT) via email at IRT@mail.nih.gov, COR, CO, the NIH Office of the SOP (or his or her designee), and other stakeholders, including incidents involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour, and consistent with the applicable NIH and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contract information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor shall:

a. cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;

b. not include any sensitive information in the subject or body of any reporting e-mail; and

c. encrypt sensitive information in attachments to email, media, etc.

Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information HHS and NIH incident response policies when handling PII breaches.

4. Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information HHS and NIH incident response policies when handling PII breaches.

5. Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to contractor facilities during a breach/incident investigation within an hour of discovery.

O. Vulnerability Scanning Reports- The Contractor shall report the results of the required monthly special vulnerability scans no later than 10 days following the end of each reporting period. If required monthly, this report may be included as part of the Technical Progress Report. Otherwise, this report shall be submitted under a separate cover on monthly basis.

P. Confidentiality and Nondisclosure of Information- Any information provided to the contractor (and/or any subcontractor) by HHS or collected by the contractor on behalf of HHS shall be used only for the purpose of carrying out the provisions of this contract and shall not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and shall ensure that all work performed by its employees and subcontractors shall be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any HHS records may be made available or disclosed shall be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein.

The confidentiality, integrity, and availability of such information shall be protected in accordance with HHS and NIH policies. Unauthorized disclosure of information will be subject to the HHS/NIH sanction policies and/or governed by the following laws and regulations:

18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);
18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and


Each employee, including subcontractors, having access to non-public Department information under this acquisition shall complete the "Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer/COR prior to performing any work under this acquisition.

17. **Electronic and Information Technology Accessibility Notice**, HHSAR 352.239-73 (December 2015)

   a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.


   c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility. In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to
assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document—in detail—whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site http://www.hhs.gov/web/508. In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

d. Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

The "HHS Section 508 Product Assessment Template" is included in SECTION J - List of Attachments, of this solicitation.

18. Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.acquisition.gov/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a. System for Award Management, FAR Provision 52.204-7 (October 2016).

Alternate I (July 2013) is not applicable to this solicitation.


c. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).


e. Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).


b. TECHNICAL PROPOSAL INSTRUCTIONS
A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

Note to Offerors: Beginning May 25, 2008, the offeror shall include the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.

1. Technical Discussions

The technical discussion included in the technical proposal should respond to the items set forth below:

a. Statement of Work

   1. Objectives

      State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

   2. Approach

      The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives. Proposals which merely restate the requirements of the Government's scope of work will not be eligible for award.

      Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

   3. Methods

      Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

   4. Schedule

      Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments of work, as applicable, by contract year as well as for the overall contract. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b. Personnel
Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

1. Single Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

2. Multiple Principal Investigators

The NIH now provides offerors the opportunity to propose a multiple Principal Investigator (PI) model on research and development contracts. The multiple PI model is intended to supplement, and not replace, the traditional single PI model. The NIH chose this RFP as a candidate for the multiple PI model. Ultimately, the decision to submit a proposal using the multiple PI versus single PI is the decision of the investigators and their institutions. The decision should be consistent with and justified by the scientific goals of the project.

It is essential that organizations consider all aspects of this approach before submitting a proposal. While there are some projects that clearly are appropriate for the multiple PI model, the "fit" of other projects may not be so clear. Offerors should base the selection of either the single PI or multiple PI option on the research proposed, to ensure optimal facilitation of the science. Projects suitable for the multiple PI model could include as few as two PIs who are jointly responsible for the scientific and technical direction of the project. The multiple PI option is based on the proposed project, not on the number of performance sites or the number of participating institutions.

Multiple PIs under research contracts shall use the Subcontract Model. In this approach, offerors submit a single proposal, and a single award is made to the prime contractor. The prime contractor, when appropriate, will award subcontracts to fund the components of the project at the other institutions. The relationship between the contractor and subcontractors must be designed to support all components of the project.

To facilitate communication with the NIH, the offeror must designate a Contact PI at the time of proposal submission. The Contact PI must be employed at the prime contractor's organization. The designation of the Contact PI may rotate on an annual basis. However, this rotation is restricted to PIs located at
the prime contractor's organization. The Contact PI is responsible for: relaying communications between all of the PIs and the NIH, and coordinating progress reports for the project. Being named Contact PI does not confer any special authority for the project.

**Leadership Plan**

Offerors proposing multiple PIs will need to submit a Leadership Plan as part of the Technical Proposal. The Leadership Plan shall describe the governance and organizational structure of the research project including communication plans, process for making decisions on scientific direction, allocation of resources, publications, intellectual property issues, and procedures for resolving conflicts. The Leadership Plan shall follow the Table of Contents provided below:

I. **Rationale**
   Include a discussion of how the project will be enhanced by the multiple PI approach.

II. **Identification of all proposed PIs**
   Identify the proposed PIs, their point of contact information and affiliated organizations, and the percentages of time proposed for this project. Identify the Contact PI and plans for rotation of that role, if any.

III. **Roles and Responsibilities**
   Identify both the scientific and administrative roles and responsibilities of all named PIs.

IV. **Approach to Fiscal and Management Coordination**
   Describe how the project will be performed and monitored from a fiscal and management perspective. Discuss organizational administrative coordination and support.

V. **Project Direction and Resource Allocation**
   Address how decisions will be made regarding scientific direction, and, how resources will be allocated and redistributed if needed during performance. Address plans for shared resources such as IT or other shared data considerations. If joint standard operating procedures will be developed, describe this process.

VI. **Communication and Lines of Authority**
   Address communication and lines of authority within and among PIs and within and among organizations.

VII. **Data sharing, Intellectual Property, Publication, and other Proprietary Considerations**
   Data sharing plans, intellectual property considerations, publication agreements, and any other proprietary or confidential information sharing should be addressed in this section.

VIII. **Conflict Resolution**
   Address how conflicts will be avoided, identified, and resolved.

IX. **Other**
   Address any other information relative to the leadership approach to Multiple PI projects.

Offerors submitting single PI proposals do not need to submit a Leadership Plan.
3. Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

4. Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

5. Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

2. Other Considerations

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d. Other factors you feel are important and support your proposed research.

e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

3. Technical Evaluation

Proposals will be technically evaluated in accordance with SECTION M - Evaluation Factors for Award of this solicitation.

4. Obtaining and Disseminating Biomedical Research Resources
As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "SHARING BIOMEDICAL RESEARCH RESOURCES: Principles and Guidelines for Recipients of NIH Research Grants and Policy," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website:


a. Sharing Research Data

[Note: This policy applies to all NIH contracts, regardless of dollar value, that are expected to generate research data.]

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:


[If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.]

5. Section 508 accessibility standards for HHS Web Site Content and Communications Materials

Regardless of format, all Web content or communications materials specifically produced for publication on, or delivery via, HHS Web sites, including text, audio, or video, under this contract shall conform to applicable Section 508 accessibility standards. Remediation of any materials that do not comply with the applicable accessibility standards of 36 CFR Part 1194 as set forth herein shall be the responsibility of the Contractor.

The following Section 508 accessibility standards apply to the content or communications material identified in this Statement of Work Performance Work Statement:
c. BUSINESS PROPOSAL INSTRUCTIONS

1. Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

2. Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when certified cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not required to be certified in accordance with FAR 15.406-2.

3. Requirements for Certified Cost or Pricing Data and Data Other than Certified Cost or Pricing Data, FAR Clause 52.215-20 (October 2010)

(a) Exceptions from certified cost or pricing data.

(1) In lieu of submitting certified cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.
(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;
(B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;
(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror’s determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for certified cost or pricing data. If the offeror is not granted an exception from the requirement to submit certified cost or pricing data, the following applies:

(1) The offeror shall prepare and submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in accordance with the instructions contained in Table 15-2 of FAR 15.408, which is incorporated by reference with the same force and effect as though it were inserted here in full text. The instructions in Table 15-2 are incorporated as a mandatory format to be used in this contract, unless the Contracting Officer and the Contractor agree to a different format and change this clause to use Alternate I.
(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 2010) of FAR Clause 52.215-20, Requirements for Certified Cost or Pricing Data and Data Other than Cost or Pricing Data (October 2010). As prescribed in 15.408(l)(and see 15.403-5(b)(1)), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b)(1) The offeror shall submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in the following format:

The format specified in paragraph L.2.c.4. Certified Cost or Pricing Data, subparagraph 3. formats for Submission of Line Item Summaries shall be used for the submission of cost data. Submission of all other certified cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

4. Salary Rate Limitation
Offerors are advised that no NIH funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level II* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level II*. The Executive Schedule, Level II* annual salary rate limitation also applies to individuals proposed under subcontracts and to consultants. **LINK TO EXECUTIVE SCHEDULE RATES OF PAY:**


(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

*Note to Offerors:* The current Fiscal Year Executive Level II Salary Rate shall be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year Executive Level II Salary rates.

5. **Mentor-Protégé Program, HHSAR 352.219-70 (December) 2015**

a. Large business prime contractors serving as mentors in the HHS Mentor-Protégé Program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU) approved mentor-protégé agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protégé firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at www.esrs.gov. The mentor firm and protégé firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a $10,000 subcontract awarded to a protégé firm and provision of $5,000 of developmental assistance as $15,000 of subcontracting plan credit.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.

b. The program consists of--

1. Mentor firms--large businesses that:
   (i) Demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and
   (ii) Have a Mentor-Protégé agreement approved by HHS’ OSDBU;

2. Protege firms--firms that:
   (i) Seek developmental assistance;
   (ii) Qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small businesses, small disadvantaged businesses, or woman-owned small businesses; and
(iii) Have a Mentor-Protege agreement approved by HHS' OSDBU; and

3. Mentor-Protege agreements--joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision)

6. HUBZone Small Business Concerns

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

7. Total Compensation Plan

   a. Instructions

   1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

   2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

   3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

   b. Evaluation

   1. Total Compensation Plan (Professional Employees)

   In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.
2. **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

3. **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

4. **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees.

8. **Other Administrative Data**

a. **Property**

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below, the proposal must include a comprehensive justification addressing the following items:

   a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.
   b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

2. **Government Property**

The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

   a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);

   b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;
c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and

d. A description of the offeror's property management system, plan, and any customary commercial practices, voluntary consensus standards, or industry-leading practices and standards to be used in the offeror in managing Government property.

NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from an offeror or contractor possessing Government property. This will be done by adjusting the offers by applying, for evaluation purposes only, a rental equivalent evaluation factor, as specified in FAR 52.245-9.

b. Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (JULY 2013)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232 34, Payment by Electronic Funds Transfer Other than System for Award Management.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9 digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9 digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

(End of Provision)

c. Financial Capacity

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d. Adequate Accounting System

FAR Part 16 sets forth the requirements and limitations for consideration of contract type. As stated in Section L.1., General Instructions of this solicitation, the resultant contract will not be Firm-Fixed Price. Therefore, the offeror's/contractor's accounting system
and practices must be adequate and suitable for accumulating costs under government contracts.

To be considered for an award under this solicitation, the offeror shall include, in the Business Proposal, the following Certification:

"By submission of its signed offer, the Offeror certifies that its accounting system:

- Complies with generally accepted accounting principles (GAAP).
- Provides for:
  - Proper segregation of direct costs from indirect costs.
  - Identification and accumulation of direct costs by contract.
  - A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
  - Accumulation of costs under general ledger control.
  - A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
  - A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
  - Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
  - Exclusion from costs charged to government contracts of amounts that are not allowable in terms of FAR 31, "Contract Cost Principles and Procedures," or other contract provisions.
  - Identification of costs by contract line item and by units (as if each unit or line item were a separate contract) if required by the proposed contract.
  - Segregation of preproduction costs from production costs, if applicable.
- Accounting system provides financial information:
  - Required by contract clause concerning limitation of cost (FAR 52.232-20) or limitation on payments (FAR 52.216-16).
  - Required to support requests for progress payments.
- Accounting system was designed, and records are maintained in such a manner that adequate, reliable data are developed for use in pricing follow-on acquisitions.
- Accounting system is currently in full operation.

The Contracting Officer reserves the right to request, with the Final Proposal Revision (FPR), a current (within 18 months) CPA opinion confirming that the Offeror's accounting system is compliant as certified above.

e. Facilities Capital Cost of Money, FAR 52.215-16, (June 2003)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.
(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] Fac Cap Cost of Money (Has) The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] Fac Cap Cost of Money (Has Not) The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

9. Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a. General Experience

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b. Organizational Experience Related to the RFP

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, but not the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c. Performance History

Performance history is defined as meeting contract objectives within delivery and cost schedules on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d. Pertinent Contracts

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e. Pertinent Grants
List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

10. **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a. Willingness to perform as a subcontractor for specific duties (list duties).
b. What priority the work will be given and how it will relate to other work.
c. The amount of time and facilities available to this project.
d. Information on their cognizant field audit offices.
e. How rights to publications and patents are to be handled.
f. A complete cost proposal in the same format as the offeror's cost proposal.

11. **Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

12. **Travel Costs/Travel Policy**

a. **Travel Costs - Commercial**
Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b. **Travel Policy**
One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.
SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost, and past performance. Although technical factors are of paramount consideration in the award of the contract and cost/price is also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost. The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the SOLICITATION. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the SOLICITATION. Offerors must submit information sufficient to evaluate their proposals based on the detailed factors listed below.

2. COST/PRICE EVALUATION

Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition, but may also be determined through cost and price analysis techniques as described in FAR 15.404.

[Cost Realism: The specific elements of each offeror(s) proposed costs are realistic when the proposed cost elements are evaluated and found to: 1) be realistic for the work to be performed; 2) reflect a clear understanding of the requirements; and 3) be consistent with the unique methods of performance and materials described in the offeror(s) technical proposal.

Cost Realism will be evaluated only on the offeror(s) inputs which the Government will use to determine the most probable cost to perform the contract in a manner consistent with the offeror's proposal. Cost realism analysis will be conducted in accordance with FAR 15.404-1(d). The result of the cost realism analysis will be considered in the making the best value tradeoff decision.]

3. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

4. EVALUATION OF DATA SHARING PLAN

The offeror’s plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.
5. TECHNICAL EVALUATION FACTORS

The evaluation factors are used by the technical evaluation committee when reviewing the technical proposals. The factors below are listed in the order of relative importance with weights assigned for evaluation purposes.

<table>
<thead>
<tr>
<th>CRITERIA</th>
<th>WEIGHT</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRITERION 1: TECHNICAL PLAN/APPROACH</td>
<td>50</td>
</tr>
<tr>
<td>Appropriateness, feasibility, and adequacy of the proposed technical plan/approach for accomplishing the tasks outlined in the Statement of Work and the overall objectives of the solicitation.</td>
<td></td>
</tr>
<tr>
<td>CRITERION 2: SCIENTIFIC AND TECHNICAL PERSONNEL</td>
<td>20</td>
</tr>
<tr>
<td>Appropriateness and adequacy of the education, training, experience, expertise, and proposed levels of effort of the Principal Investigator and scientific and technical staff including subcontractors/consultants for accomplishing the tasks outlined in the Statement of Work and the overall objectives of the solicitation.</td>
<td></td>
</tr>
<tr>
<td>CRITERION 3: PROJECT MANAGEMENT</td>
<td>20</td>
</tr>
<tr>
<td>Appropriateness and adequacy of the Project Management Plan in terms of staffing, organizational structure and lines of authority, management of subcontracts/consultants, tracking of project activities, monitoring progress and timelines, and communication with stakeholders.</td>
<td></td>
</tr>
<tr>
<td>CRITERION 4: FACILITIES, EQUIPMENT, AND OTHER RESOURCES</td>
<td>10</td>
</tr>
<tr>
<td>Appropriateness and adequacy of facilities, equipment, space and other resources including those of subcontractors/consultants for accomplishing the tasks outlined in the Statement of Work and the overall objectives of the solicitation.</td>
<td></td>
</tr>
</tbody>
</table>

TOTAL POSSIBLE WEIGHT: 100

6. EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY - SECTION 508

The offeror's proposal must demonstrate compliance with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194 for all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order, including EIT deliverables such as electronic documents and reports.

If your proposal does not include a completed HHS "Section 508 Product Assessment Template" (hereafter referred to as the "Template") which demonstrates that EIT products and services proposed support applicable Section 508 accessibility standards, or, if the completed "Template" included in your proposal is considered "noncompliant," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify the "Template" during discussions and in your Final Proposal Revision (FPR). If your "Template" is still considered "noncompliant" by the Government after discussions, your proposal may not be considered further for award.

7. PAST PERFORMANCE FACTOR

Offeror's past performance information will be evaluated subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.
The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.
I. PROPOSAL SUBMISSION

A. eCPS

   1. The National Institute of Allergy and Infectious Diseases (NIAID) requires proposals to be submitted via its electronic Proposal Submission System (eCPS).
   2. Submission of proposals by facsimile or e-mail is not acceptable.
   3. Follow the “How to Submit an Electronic Proposal” instructions provided on the eCPS website at: https://ecps.nih.gov/NIAID/home/howto. Please note that creating an account to submit can take up to three (3) business days. Please register early to allow enough time for the registration process.
   4. Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated above by the date and time specified in the solicitation. If your proposal is not received by the date and time specified in the solicitation, it will be considered a “late proposal”, in accordance with FAR Clause 52.215-1 Instructions to Offerors – Competitive Acquisition.

B. Creating and Naming Files:

   1. Create one PDF file of your Technical Proposal, including all attachments. The Technical Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned, but must be merged into the Technical Proposal PDF file.
   2. The Business Proposal must be comprised of the following files:
      a. The first file must be a PDF of your Business Proposal, with all attachments, including the Solicitation Section J, Attachment entitled “Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet.” The Business Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned and merged into the Business Proposal PDF file.
      b. The remaining file(s) should be the “Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet” in its original Excel format, not PDF. Multiple Excel files may be included, as necessary.
   3. Each of the proposals, Technical and Business, must be separate and complete in itself, so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other.
   4. File naming convention: It is required that the filenames for both your Technical Proposal, Business Proposal, and Excel Workbook include the name of the offeror,
the solicitation number, and the type of proposal (i.e., Technical, Business, or Excel Workbook).

Examples:
Business Proposal: XYZ Company_NIHAI2012001_Business.pdf
Excel Workbook: XYZ Company_NIHAI2012001_Business.xlsx

II. FORMATTING AND PAGE LIMITATIONS:

A. Formatting for proposals

1. Proposals shall not include links to internet web site addresses (URLs) or otherwise direct readers to alternate sources of information.
2. Font size must be 10 to 12 points.
3. Spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
4. Margins must be at least one-inch on all sides.
5. Failure to adhere to the formatting requirements above may impact whether your proposal is reviewed in entirety.

B. Page limitations:

1. Total page count does not include: Title and Back Page; Table of Contents; Section Dividers that do not contain information other than title of Section.
2. Pages in excess of this limitation of 150 pages of the technical proposal will be removed and will not be considered.
ATTACHMENT 2: PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIAID-DAIT-NIHAI201800018
RFP Title: CIVICs Statistical, Data Management and Coordination Center (SDMCC)

Please review the attached Request for Proposal (RFP). Furnish the information requested below and return this page by October 15, 2018. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

[ ] DO INTEND TO SUBMIT A PROPOSAL

[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): ______________________________________
Address (print): _______________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

Project Director's Name (print): _________________________________________
Title (print): ___________________________________________________________
Signature/Date: _________________________________________________________
Telephone Number and E-mail Address (print clearly):
_____________________________________________________________________
_____________________________________________________________________

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
OA, NIAID, NIH
Room 3B59
5601 Fishers Lane, MSC 9821
Rockville, MD 20852
Attn: Maribel Miranda
RFP-NIAID-DAIT-NIHAI201800018
FAX 301-451-5430
Email: Maribel.Miranda@nih.gov
1) **BACKGROUND AND INTRODUCTION**

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), strives to understand, treat and ultimately prevent the myriad of infectious, immunologic, and allergic diseases that threaten millions of human lives. As part of this research program, NIAID supports a comprehensive portfolio covering basic, translational and clinical studies to improve the efficacy of seasonal influenza vaccines, including development of a universal vaccine that will provide broad, durable protection against group I and II influenza A viruses. NIAID also provides resources, including animal models, research reagents and testing of candidate products, to investigators worldwide to facilitate biomedical research and help move drugs, vaccines and diagnostics closer to clinical use. In addition, NIAID supports a robust program in basic immunology that includes detailed analyses of human immune responses to pathogenic infections and/or vaccines. The NIAID Divisions of Allergy, Immunology and Transplantation (DAIT) and Microbiology and Infectious Diseases (DMID) have jointly developed the Collaborative Influenza Vaccine Innovation Center (CIVICs) program ([HHS-NIH-NIAID-BAA2018 Amendment 1](#)) to advance the production of improved seasonal and universal influenza vaccines that provide durable, broadly cross-protective immunity. This current solicitation supports the establishment of a Statistical, Data Management and Coordination Center (SDMCC) that will provide statistical support, data management and analysis, and preclinical/clinical study coordination services for the CIVICs program, which includes at least two (2) Vaccine Centers, responsible for design/development and comprehensive immunologic evaluation of candidate influenza vaccines both preclinically and clinically; a Vaccine Manufacturing and Toxicology Core, which manufacture, formulate, optimize, and evaluate the safety and toxicity of the innovative vaccine platforms and approaches developed by the Vaccine Centers; and a Clinical Core, which will conduct vaccine and human challenge trials.
NIAID anticipates making one term, level-of-effort (LOE), severable award for the SDMCC. The total performance period comprised of the base and any options shall not exceed seven (7) years, in alignment with the CIVICs program. Awards are anticipated to be made in or around August 2019.

2) **SCOPE**

The Contractor shall establish and manage a Statistical, Data Management and Coordination Center (SDMCC) that will support the CIVICs program through: facilitating statistically sound preclinical and clinical study design; enabling data analyses and data sharing across the CIVICs program; conducting/coordinating submission of CIVICs data and meta-data to NIAID-designated public repositories; developing and maintaining a CIVICs public portal; tracking and sharing of CIVICs-generated samples, reagents, resources, and standard operating procedures (SOPs) across the CIVICs program and with the broader research community; and managing initiation, conduct, and tracking of CIVICs-related clinical trials and human challenge studies.

3) **TECHNICAL REQUIREMENTS**

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work as stated herein. Specifically, the Contractor shall:

1. **Statistical Design and Analysis**
   a. Statistical Design
i. Provide statistical design assistance for preclinical and clinical studies developed by CIVICs investigators, including sample size and power calculations;

ii. Develop and refine study designs and statistical analysis plans for NIAID-approved clinical studies and clinical trials, including human challenge studies, conducted by CIVICs investigators in collaboration with the CIVICs-associated Clinical Core; and

iii. Arrange for and participate in the review of successive versions of clinical protocols and recommend improvements and modifications in statistical design and statistical analysis plans.

b. Statistical Analysis

i. Utilize state-of-the-art statistical analysis tools and data integration methods for comprehensive immunologic data generated through the CIVICs preclinical and clinical studies, to facilitate the identification of immune correlates of protection and assist in selection of promising vaccine candidates;

ii. Prepare interim and final statistical analyses of all pre-clinical and clinical study data in collaboration with CIVICs-supported investigators;

iii. Participate in preparing scientific manuscripts and reports for publication and presentation;

iv. Review the accuracy and completeness of statistical analyses included in abstracts, manuscripts and presentations reporting on the results of research conducted by the CIVICs program;

v. Provide statistical analyses support for the CIVICs program in connection with regulatory requirements and activities for clinical trials conducted under Investigational New Drug Applications (INDs) (e.g., materials preparation and oral presentations on statistical design and analysis plans and issues for discussions with and inquiries from the U.S. Food and Drug Administration (FDA) and other Regulatory Health Authorities);

vi. Prepare regular statistical reports such as periodic study status reports, Data Safety Monitoring Board/Safety Monitoring Committee (DSMB/SMC) reports, mechanistic analysis reports and components of Interim and Final Clinical Study Reports; and

vii. Partner in preparing materials for and make oral presentations at DSMB/SMC meetings/teleconferences regarding interim and final safety data and, on an as-needed basis, in preparing written summaries of DSMB/SMC deliberations.

2. Data Management and Analysis

Operate and maintain a scalable, flexible data management system for the collection, management, storage, quality control, analysis, sharing and query/retrieval of all preclinical and clinical data generated by the CIVICs program. The system must be interoperable with and based on the data
standards developed to date by the NIAID-funded ImmPort (www.immport.org), the Immune Epitope Database and Analysis Resource (www.iedb.org), the Bioinformatics Resource Centers (www.fludb.org), the Centers of Excellence for Influenza Research and Surveillance (CEIRS) (http://www.niaidceirs.org/), Clinical Research Management Systems and other relevant NIAID-designated databases/repositories. The system shall be extensible without major refactoring to support new data types generated by the CIVICs program. Protection of data generated by the CIVICs program shall be consistent with NIAID Federal Information Management Security (FISMA) requirements. In addition, all clinical systems of record must be compliant with 21.CFR.11 and ICHE6R2. Tasks shall include:

a. Implement software tools to facilitate collection, harmonization, tracking, updating, query, visualization and analysis of metadata, experimental data and information generated across the CIVICs program, including by not limited to:
   i. Data entry solutions via the internet for all CIVICs-supported investigators;
   ii. Support and manage the sharing, transfer and access of viral genome sequences; vaccine composition and formulation; serologic and immunologic data, including hemagglutination and neuraminidase inhibition, microneutralization, immune receptor repertoire analyses, multi-parameter flow cytometry, CyTOF, proteomics, metabolomics, transcriptomics, RNA-seq; clinical trial and human challenge study data, and all relevant metadata;
   iii. Assist the CIVICs program with advanced analysis and integration of complex systems immunology, functional analyses of T cell responses, serum proteomic analyses in combination with B cell clonal profiling to establish the clonal origin of serum antibodies, and a wide range of diverse datasets, including importing data from related projects to facilitate data mining and analyses and keeping abreast of emerging technologies and data analysis and integration tools;
   iv. Support and manage vaccine manufacturing, formulation and toxicology metadata and data collection and tracking;
   v. Generate periodic reports on status of specific studies, data sets, and across the data sets for multiple parameters; and
   vi. Provide training and consultation on using SDMCC-supported data, software and computing resources to the CIVICs investigators.

b. Data Quality Control: Establish a quality control system for all clinical, laboratory, vaccine manufacturing and toxicology testing, and Serious Adverse Events (SAEs) data providing for verification of 100 percent of study data and multiple features and capabilities, including:
   i. Automated validation and error-checking;
ii. Strategies to ensure uniform, standardized data collection and appropriate conduct of multi-center studies across participating study sites; ongoing quality assurance and quality control checks and summaries of results; and ability to query for aberrant and/or missing data; and

iii. Prepare and review and revise, on an annual basis, manuals and procedures documenting data collection, editing and validation standards and procedures.

c. Management of clinical trial and human challenge data, that includes:
   i. Electronic registration and randomization of the majority of subjects and non-computerized methods on a limited basis;
   ii. Electronic study forms and systems for remote data entry and transmission, via the internet, of subject data from study sites and laboratories and non-computerized transmission methods when necessary, which are in compliance with HIPAA regulations;
   iii. Data links to and interoperability with the NIAID Clinical Research Management System (CRMS: https://ncrms.niaid.nih.gov) to provide enrollment and study status updates;
   iv. Real-time electronic notification to NIAID staff and clinical investigators in instances where one or more protocol-specific or NIAID safety review committee-specific data trigger halting rule(s);
   v. Generate periodic reports on status of clinical trials and human challenge studies; and
   vi. Establish and operate an electronic system, with appropriate system security and integrity procedures, to monitor, track, archive and report SAEs from all clinical sites, providing for multiple features and capabilities, including:
      i. An online tracking system for the receipt, reporting and disposition of SAEs;
      ii. Work flow processes utilizing established safety data management systems for collecting SAE Reports from participating clinical sites, SOPs for SAE reporting, and training clinical site personnel in system use;
      iii. Protocol-specific SAE reporting forms and instructions;
      iv. A telephone help line to respond to inquiries about clinical events and obtain SAE Report information;
      v. Evaluation of all SAE Reports submitted, within one business day of receipt, by Center nursing/safety desk staff;
      vi. Provide SAE documents and disposition forms to NIAID utilizing, in part, the NIAID Clinical Research Information System (CRIS);
      vii. Real-time electronic notification of SAEs to NIAID medical and scientific staff, CIVICs clinical investigators, NIAID
DSMBs/SMCs and Statistical and Clinical Coordinating Committee (SACCC) staff; and

viii. Compliance with U.S. and non-U.S. regulations and requirements for the collection, verification and processing of SAE Reports and safety information.

d. Participate in preparing scientific manuscripts and reports for publication and presentation.

When implementing these data management activities, the Contractor also shall:

a. Coordinate with and assist the CIVICs program to manage, report and transfer all data and resources generated to the SDMCC data management system/portal including developing and implementing data sharing and access plans with timelines and descriptions of data sets to be shared;

b. Conduct and/or facilitate the transfer and submission of data collected from the CIVICs program to appropriate publicly-accessible databases, including the NIAID-funded Bioinformatics Resource Centers (www.fludb.org), ImmPort (www.immport.org), Immune Epitope Database (www.iedb.org), NCBI resources, and other relevant databases as designated by NIAID for wide dissemination; and

c. As directed by CO and COR, participate in ongoing development efforts and data and meta-data standards efforts of the ImmPort, IEDB, CEIRS, BRCs and other relevant databases/repositories for diverse data types and clinical metadata generated by the CIVICs program to ensure interoperability and data sharing.

3. **CIVICs Program Data Access and Resource Sharing**

Within 90 calendar days after the effective date of the contract, establish, maintain and update one portal capable of controlled access for sharing research data and information with the COR, other relevant NIAID staff, and the CIVICs program, and for providing public access to information about the CIVICs program, as directed by the COR. The capabilities of the portal shall include, and may not be limited to the following:

a. Browse collected data from CIVICs sites;

b. Query the data to address tracking and reporting requirements of CIVICs;

c. Community access to information about results and resources generated by the CIVICs program, including pointing the public to CIVICs data sets
housed in NIAID-supported or other databases, publications lists, meeting updates, vaccine candidates in clinical testing, etc.; and

d. Adopt and implement FAIR data-sharing guidelines in data management, access and sharing solutions that enable and ensure interoperability and subsequent dissemination through NIAID-supported or other public repositories and knowledgebases.

4. CIVICs Program Coordination Services

a. Develop and maintain a component of the SMDCC system that contains:
   i. Standard Operating Procedures (SOPs) for sample collection, processing and storage for all pre-clinical and clinical studies/trials, and protocols for all the assays developed or used by the CIVICs program;
   ii. A record of the location and status of all samples (animal and human) reagents, and vaccines collected or generated by the CIVICs program to facilitate sharing/distribution across the CIVICs program and with the broader research community;
   iii. A list and summation of CIVICs program publications (with PubMed links); and
   iv. Curation of relevant information from previously published or new manuscripts of importance as identified and assigned by the COR.

b. CIVICs site training, assessment and technical assistance.
   i. Prepare and make available to the CIVICs program a data submission user’s manual and standard operating procedures (SOPs);
   ii. Establish and maintain a support system to receive and respond to data management questions and requests for assistance from CIVICs sites;
   iii. Prepare instructional materials for CIVICs program staff, including study investigators, site coordinators, research nurses, monitors and, where applicable, data managers and data entry personnel, via meetings, conference calls and webcasts. Training topics shall include: design of data collection materials; data entry; data management; data validation; audit trails; and use of the electronic specimen tracking system. Training may be provided in a variety of settings including at CIVICs sites or at group meetings;
iv. Training of Clinical Site Personnel: provide training to clinical site personnel on data collection instruments and procedures for data collection, entry, management, validation, quality control and submission through user manuals and participation in Study Initiation activities;

v. Provide support for certain functions associated with safety monitoring by independent DSMBs/SMCs established by the CIVICs Clinical Core to review final clinical protocols and interim and final study data to ensure the safety of clinical trial subjects, including: assembling materials for DSMB/SMC review (e.g., final draft clinical protocols, protocol amendments, statistical analyses, etc.); archiving DSMB/SMC materials; and assisting in preparing and coordinating communications with NIAID staff, and clinical site personnel in instances where NIAID accepts a DSMB/SMC recommendation to change an ongoing study;

vi. Clinical Study Initiation and Training of Clinical Site Personnel:
   i. Assist in planning and developing materials for and participate in study initiation meetings, teleconferences, webcasts and videocasts, to provide standard and study-specific training for clinical site personnel in multiple areas, e.g., key features, procedures and requirements for study implementation, data collection instruments and procedures for data collection, entry, management, validation, quality control and submission, and standard and study-specific procedures and instructions for AE and SAE reporting. Coordinate planning and materials development for study initiation activities with other appropriate CIVICs investigators, NIAID staff and clinical trial site investigators;
   ii. Plan and conduct training programs for clinical site personnel covering regulatory requirements and standard practices for human subject research, DHHS (Department of Health and Human Services), NIH and NIAID policies, and policies and procedures used by NIAID and NIAID-supported clinical research programs for protocol development, implementation, monitoring and reporting; and
   iii. Prepare and provide to clinical site personnel Standard Operating Procedures (SOPs) covering all such policies, procedures and requirements, and working with NIAID and clinical site staff to identify site-specific training needs.

vii. Clinical Trial Standard Operating Procedures (SOPs)
   i. Develop and implement SOPs governing all aspects of the support to be provided, e.g., all types of visits, descriptions of each aspect of clinical trial conduct and
clinical site operations to be reviewed, detailed work instructions, etc.;
ii. Develop and implement SOPs to provide monitoring reports and other related data to NIAID utilizing the NIAID CRIS;
iii. Keep abreast of all changes in Federal and country-specific requirements for human subject research and good practice guidelines, update SOPs as necessary, and ensure appropriate training of CIVICs program staff on new requirements/guidelines; and
iv. Develop and implement a process to collect, review and respond to user feedback, in consultation with NIAID, to improve the usability and functionality of the data management system and portal for the storage and retrieval of preclinical and clinical data generated by the CIVICs program (Technical Requirements Sections 2 and 3, above), and of the public portal that provides community access to information about results and resources generated by the CIVICs (Technical Requirements Section 3.c, above).

c. Development, maintenance, and revision of a Quality Management Plan to ensure that Quality Control and Assurance metrics are met for all activities conducted by the SDMCC. A Quality Management Report shall be provided to NIAID on recurring basis as outlined in Table b. of ATTACHMENT 2: REPORTING REQUIREMENTS AND DELIVERABLES.

5. Final Transition: Provide plans for an orderly, secure, and efficient transition of contract activities and contract-related data, documents and other materials to another contractor in the event that a transition is required.

Option(s)

In addition to the services/quantities outlined above to be provided for the base requirement, Options(s) for additional services/quantities under the contract may be exercised at the discretion of the Government and are defined as follows:

Option 1 - 6: Extend the Term of the Contract: The Government may include options to extend the period of the performance. The total period of
performance resulting from the base period plus all potential Term Options is seven [7] years. If Option 1-6 are exercised, the services required will be the same as provided during the base year.

**Option 7 - 41: Increase Level of Effort:** The Government may exercise options for increased level of effort that may result from unanticipated increases in demand, as the CIVICs program activities increase. Should the Government elect to exercise these options, the Contractor shall provide resources for the unanticipated increase in work volume by half [0.5] FTEs for each option exercised, with a maximum of five (5) options (i.e., 2.5 additional FTEs) being exercised in the base year and in each option year thereafter.
ATTACHMENT 4: ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS, FORMAT FOR TECHNICAL PROPOSAL, and TABLE OF CONTENTS

CIVICs Statistical, Data Management and Coordination Center (SDMCC)

RFP-NIAID-DAIT-NIHAI201800018

It is strongly recommended that offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the Technical Proposal should be presented in the order specified below.

These additional Technical Proposal instructions reflect the requirements of the solicitation and provide specific instructions and formatting for the Technical Proposal. While Section L of the solicitation provides a generic set of Technical Proposal instructions applicable to all NIH R&D solicitations, these instructions are tailored to the specific requirements of the RFP. The information requested in these instructions should be used to format and prepare the Technical Proposal, and should be used as a Table of Contents for your Technical Proposal. Offerors should follow the instructions in Section L of the solicitation, and include the information requested here.

Offerors are advised to give careful consideration to the Statement of Work, all reference materials, and attachments, the Technical Evaluation Criteria in Section M, and the solicitation as a whole in the development of their Technical Proposals.

Offerors proposing subcontracts to perform portions of the Statement of Work should clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration/coordination between the prime Contractor and all proposed subcontractors, and the expected advantages of such an approach.
TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1:

1) PROPOSAL TITLE PAGE. Include RFP title and number, name of organization, DUNS number, and identify if the proposal is an original or a copy. Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall also include the legend regarding Restriction on Disclosure and Use of Data prescribed by FAR 52.215-1 (e)]

2) TABLE OF CONTENTS

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (suggested 3-page maximum)

Provide a brief overview of the Technical Proposal, including:

1) A brief description of the activities proposed by the offeror and all proposed subcontractors, including identification of all proposed subcontractors and a list of key personnel for the offeror and the proposed subcontractors with degrees, titles and role in the project.
2) By area of expertise, provide the total number of staff, the number available to be assigned to the contract for the offeror and all proposed subcontractors, and total number of additional staff to be hired and trained.
3) A brief description of the facilities and equipment to be made available by the offeror and all proposed subcontractors.

SECTION 3: TECHNICAL PLAN/APPROACH
Provide a detailed description of the rationale, plans and procedures for conducting the following activities:

1. Statistical Design and Analysis
   a. Statistical Design
      i. Providing statistical design assistance for preclinical and clinical studies developed by CIVICs investigators, including sample size and power calculations;
      ii. Developing and refining study designs and statistical analysis plans for NIAID-approved clinical studies and clinical trials, including human challenge studies, conducted by CIVICs investigators in collaboration with the CIVICs-associated Clinical Core; and
      iii. Arranging for and participating in the review of successive versions of clinical protocols and recommend improvements and modifications in statistical design and statistical analysis plans.
   b. Statistical Analysis
      i. Statistical analyses and data integration methods for comprehensive immunologic data generated through the CIVICs preclinical and clinical studies, to facilitate the identification of immune correlates of protection and assist in selection of promising vaccine candidates;
      ii. Preparing interim and final statistical analyses of all pre-clinical and clinical study data in collaboration with CIVICs-supported investigators;
      iii. Participating in preparing scientific manuscripts and reports for publication and presentation;
      iv. Reviewing the accuracy and completeness of statistical analyses included in abstracts, manuscripts and presentations reporting on the results of research conducted by the CIVICs program;
      v. Providing statistical analyses support for the CIVICs program in connection with regulatory requirements and activities for clinical trials conducted under Investigational New Drug Applications (INDs) (e.g., materials preparation and oral presentations on statistical design and analysis plans and issues for discussions with and inquiries from the U.S. Food and Drug Administration (FDA) and other Regulatory Health Authorities);
      vi. Preparing regular statistical reports such as periodic study status reports, DSMB/SMC reports, mechanistic analysis reports and components of Interim and Final Clinical Study Reports; and
      vii. Partnering in preparing materials for and make oral presentations at DSMB/SMC meetings/teleconferences regarding interim and final safety data and, on an as-needed basis, in preparing written summaries of DSMB/SMC deliberations.
2. Data Management and Analysis

Detailed plans and procedures for operating and maintaining a scalable data management system for the collection, management, storage, quality control, analysis, sharing and query/retrieval of all preclinical and clinical data generated by the CIVICs program, including how the system will be made interoperable with and based on the data standards developed to date by the NIAID-funded ImmPort (www.immport.org), the Immune Epitope Database and Analysis Resource (www.iedb.org), the Bioinformatics Resource Centers (www.fludb.org), the Centers of Excellence for Influenza Research and Surveillance (CEIRS) (http://www.niaidceirs.org/), and NIAID Clinical Research Management Systems. Describe how the clinical systems of record will be compliant with 21.CFR.11 and ICHE6R2, including the clinical data management system that will be used.

Describe how the system will be extensible without major refactoring to support new data types generated by the CIVICs program; and how protection of data generated by the CIVICs program shall be consistent with NIAID Federal Information Management Security (FISMA) requirements and 21.CFR.11, where required; how data sharing will be addressed including establishing appropriate data access guidelines, data use agreements and data sharing policies that are consistent with the NIH https://grants.nih.gov/policy/sharing.htm, NIAID Data Sharing and Release Guidelines https://www.niaid.nih.gov/research/data-sharing-and-release-guidelines, and the NIH Notice for Use of Cloud Computing Services for Storage and Analysis of Controlled-Access Data Subject to the NIH Genomic Data Sharing Policy as https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-086.html applicable; and the plans and procedures for:

a. Implementing software tools to facilitate collection, harmonization, tracking, updating, query, visualization and analysis of metadata, experimental data and information generated across the CIVICs investigators, including by not limited to:

i. Data entry solutions via the internet for all CIVICs-supported investigators;

ii. Support of viral genome sequences; vaccine composition and formulation; serologic and immunologic data, including hemagglutination and neuraminidase inhibition, microneutralization, immune receptor repertoire analyses, multi-parameter flow cytometry, CyTOF, proteomics, metabolomics, transcriptomics, RNA-seq; clinical trial and human challenge study data, and all relevant metadata;

iii. Assisting the CIVICs program with advanced analysis and integration of complex systems immunology, functional analyses of T cell responses, serum proteomic analyses in combination with B cell clonal profiling to establish the clonal origin of serum antibodies, and a wide range of diverse datasets, including importing data from related projects to facilitate data mining and analyses and keeping abreast of emerging technologies and data analysis and integration tools;

iv. Supporting vaccine manufacturing, formulation and toxicology metadata and data collection and tracking;

v. Generating periodic reports on status of specific studies, data sets, and across the data sets for multiple parameters; and
vi. Providing training and consultation on using SDMCC-supported data, software and computing resources to the CIVICs investigators.

b. Establishing a quality control system for all clinical, laboratory, vaccine manufacturing and toxicology testing, and Serious Adverse Events (SAEs) data providing for verification of 100 percent of study data and multiple features and capabilities, including:
   i. Automated validation and error-checking;
   ii. Strategies to ensure uniform, standardized data collection and appropriate conduct of multi-center studies across participating study sites; ongoing quality assurance and quality control checks and summaries of results; and ability to query for aberrant and/or missing data; and
   iii. Preparing, reviewing and revising manuals and procedures documenting data collection, editing and validation standards and procedures.

c. Management of clinical trial and human challenge data, including:
   i. Documentation of what identifiable human data will be collected and how the data storage and retrieval methods will be compliant with HIPAA requirements;
   ii. Electronic registration and randomization of the majority of subjects and non-computerized methods on a limited basis;
   iii. Electronic study forms and systems for remote data entry and transmission, via the internet, of subject data from study sites and laboratories and non-computerized transmission methods when necessary;
   iv. Data links to and interoperability with the NIAID Clinical Research Management System (CRMS: https://ncrms.niaid.nih.gov) to provide enrollment and study status updates; and
   v. Real-time electronic notification to NIAID staff and clinical investigators in instances where one or more protocol-specific or NIAID safety review committee-specific data trigger halting rule(s).

vi. Establishing and operating an electronic system, with appropriate system security and integrity procedures, to monitor, track, archive and report SAEs from all clinical sites, providing for multiple features and capabilities, including:
   i. Online tracking system for the receipt, reporting and disposition of SAEs;
   ii. Work flow processes utilizing established safety data management systems for collecting SAE Reports from
participating clinical sites, SOPs for SAE reporting, and training clinical site personnel in system use;

iii. Protocol-specific SAE reporting forms and instructions;

iv. Telephone help line to respond to inquiries about clinical events and obtain SAE Report information;

v. Evaluating all SAE Reports submitted, within one business day of receipt, by Center nursing/safety desk staff;

vi. Providing SAE documents and disposition forms to NIAID utilizing, in part, the NIAID CRIS;

vii. Real-time electronic notification of SAEs to NIAID medical and scientific staff, clinical investigators, NIAID DSMBs/SMCs and SACCC staff; and

viii. Complying with U.S. and non-U.S. regulations and requirements for the collection, verification and processing of SAE Reports and safety information.

d. Participation in preparing scientific manuscripts and reports for publication and presentation.

The offeror shall also describe the procedures and plans for:

a. Coordinating with and assist the CIVICs program to manage, report and transfer all data and resources generated to the SDMCC data management system/portal including developing and implementing data sharing and access plans with timelines and descriptions of data sets to be shared;

b. Conducting and/or facilitating the transfer and submission of data collected from the CIVICs program to appropriate publicly-accessible databases; and

c. Engaging with ongoing development efforts and data and meta-data standards efforts of the ImmPort, IEDB, CEIRS, BRCs and other relevant databases/repositories for diverse data types and clinical metadata generated by the CIVICs program to ensure interoperability and data sharing.

3. CIVICs Program Data Access and Resource Sharing

Detailed plans and procedures for establishing, maintaining and updating a single portal capable of privately sharing research data and information with the COR, other relevant NIAID staff, and the CIVICs program, and for providing public access to information about the CIVICs program, as directed by the COR; and including the following capabilities:

a. Browsing collected data from CIVICs sites;

b. Querying the data to address tracking and reporting requirements of CIVICs;
c. Providing public access to information about results and resources generated by the CIVICs program; and
d. Adopting and implementing FAIR data-sharing guidelines that enable and ensure interoperability and subsequent dissemination through NIAID-supported or other public repositories and knowledgebases.

4. CIVICs Program Coordination Services

a. Detailed plans and procedures for the development and maintenance of a component of the SMDCC system that contains:
   i. Standard Operating Procedures (SOPs) for sample collection, processing and storage for all pre-clinical and clinical studies/trials, and protocols for all the assays developed or used by the CIVICs program;
   ii. A record of the location and status of all samples (animal and human) reagents, and vaccines collected or generated by the CIVICs investigators to facilitate sharing/distribution across the CIVICs program and with the broader research community;
   iii. A list and summation of CIVICs program publications (with PubMed links); and
   iv. Curation of relevant information from previously published or new manuscripts of importance.

b. Detailed plans and procedures for providing CIVICs site training, assessment and technical assistance, including:
   i. Preparing and providing the CIVICs program a data submission user's manual and standard operating procedures (SOPs);
   ii. Establishing and maintaining a support system to receive and respond to data management questions and requests for assistance from CIVICs sites;
   iii. Preparing instructional materials for CIVICs staff, including study investigators, site coordinators, research nurses, monitors and, where applicable, data managers and data entry personnel, via meetings, conference calls and webcasts;
   iv. Training of Clinical Site Personnel: describe the training locations and topics to be covered. Providing support for certain functions associated with safety monitoring by independent DSMBs/SMCs established by the CIVICs Clinical Core to review final clinical protocols and interim and final study data to ensure the safety of clinical trial subjects; and
   v. Clinical Study Initiation and Training of Clinical Site Personnel:
      i. Assisting in planning and developing materials for and participate in study initiation meetings, teleconferences, webcasts and videocasts, to provide standard and
study-specific training for clinical site personnel in multiple areas, and coordinating the planning and materials development for study initiation activities with other appropriate CIVICs investigators, NIAID staff and clinical trial site investigators;

ii. Planning and conducting training programs for clinical site personnel covering regulatory requirements and standard practices for human subject research, DHHS (Department of Health and Human Services), NIH and NIAID policies, and policies and procedures used by NIAID and NIAID-supported clinical research programs for protocol development, implementation, monitoring and reporting; and

iii. Preparing and providing clinical site personnel Standard Operating Procedures (SOPs) covering all such policies, procedures and requirements, and working with NIAID and clinical site staff to identify site-specific training needs.

vi. Clinical Trial Standard Operating Procedures (SOPs)
   i. Developing and implementing SOPs governing all aspects of the support to be provided, e.g., all types of visits, descriptions of each aspect of clinical trial conduct and clinical site operations to be reviewed, detailed work instructions, etc;

   ii. Developing and implementing SOPs to provide monitoring reports and other related data to NIAID utilizing the NIAID CRIS; and

   iii. Keeping abreast of all changes in Federal and country-specific requirements for human subject research and good practice guidelines, update SOPs as necessary, and ensure appropriate training of CIVICs staff on new requirements/guidelines.

viii. Collecting, reviewing and responding to user feedback to improve the usability and functionality of the data management system and portal for the storage and retrieval of preclinical and clinical data generated by the CIVICs program, and of the public portal that provides community access to information about results and resources generated by the CIVICs program.

c. Description of the Quality Management Plan of how Quality Control and Assurance measures will be conducted for all relevant SDMCC activities, including how these measures will be accomplished and which related metrics will be captured and reported to NIAID.
SECTION 4: SCIENTIFIC AND TECHNICAL PERSONNEL

Provide information relevant to document individual training, experience, qualifications and expertise necessary for the successful completion of all contract requirements. Limit CVs to 2-3 pages and provide selected references for publications relevant to the scope of the contract.

1) **Principal Investigator (PI):** Describe the experience, training, expertise, and qualifications, and level of effort of the proposed Principal Investigator to lead and direct the activities to be carried out under this contract. In particular, address scientific and technical expertise/experience in: statistics, data science, virology, immunology and clinical trial oversight.

2) **Other Key Scientific and Technical Personnel:** Describe the experience, training, expertise and qualifications, as well as the level of effort, for all proposed key scientific and technical personnel. In particular address scientific and technical expertise in statistics, data science, bioinformatics, computational biology, influenza virology, immunology including systems immunology, vaccinology, and clinical trial management and regulatory affairs.

SECTION 5: FACILITIES, EQUIPMENT, AND OTHER RESOURCES

The Technical Proposal should document availability and adequacy of facilities, equipment, space and other resources necessary to carry out the Statement of Work, including:

1) Location and features of facilities including a floor plan and a list of equipment and resources dedicated to the project for the prime contractor and any proposed subcontractors (lease or ownership information should be provided).

2) Identification and description of ALL support resources (including Information Technology systems) that will be required to effectively complete the SOW.

SECTION 6: PROJECT MANAGEMENT

1) Provide a Project Management Plan for the overall organization that addresses the planning, initiation, implementation, conduct, monitoring and completion of tasks identified in the Statement of Work. If consultants and/or subcontractors are proposed, include a plan to manage, coordinate, and oversee the work performed by consultants and/or subcontractor(s).
2) Provide a Staffing Plan that describes roles, responsibilities, and level of effort for all scientific and technical personnel, including all proposed subcontractors and consultants. Provide an administrative and technical framework indicating clear lines of authority and responsibility for all proposed personnel. Include a chart of the proposed organizational/management structure for the project.

3) Describe the project management systems that will be used to track activities and to keep multiple activities on time and budget. The plan must include a description of the quality control methods that will be used to ensure the effective and efficient initiation, implementation, management, and oversight of contract requirements.

4) Outline how the PI (or Project Manager) will communicate with the Contracting Officer’s Representative and Contracting Officer and how the PI (or Project Manager) will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities), including how the Contractor will accommodate Level of Effort increases as requested by NIAID to meet growing needs of the CIVICs program.

SECTION 7: OPTIONS

Options should be presented as a separate part of the Technical Proposal and clearly identified as such.

1) OPTIONS 1 through 6: Extend the Term of the Contract

Discuss plans and procedures for continuing and providing the same services indicated in the Statement of Work beyond the contract base period. To address this option, offerors should describe the methods and procedures to maintain the operations specified in the Statement of Work beyond the base period, including retaining or recruiting necessary staff, and maintaining and/or acquiring required equipment and facility space.

2) OPTION 7 – 41: Increase Level of Effort

Discuss approaches for incrementally increasing the level of effort by 1,040 hours direct labor hour increments to respond to the need for unanticipated
additional capacity related to the research conducted in accordance with the Statement of Work. A maximum of five (5) options (i.e., 2.5 additional FTEs) may be exercised in the base year, and in each option year thereafter.

SECTION 8: OTHER CONSIDERATIONS

Other than those detailed in the Government Furnished Property clause or otherwise publicly available, the offeror shall not propose government furnished resources, to include government employees, facilities, intellectual property or biological materials. If you propose government furnished resources your proposal will not be considered further for award.
In addition to the format requirements for the Business Proposal that are contained in Section L of the solicitation, the information presented in this section of the RFP is intended to provide uniform cost assumptions and business clarifications.

Offerors are advised to give careful consideration to the Statement of Work, all reference material provided as attachments, the Technical Evaluation Criteria, and the RFP as a whole, in the development of your proposal. The information requested in these instructions should be used as a guide for the development and formatting of your Business Proposal. Offerors should consider and include the information requested here, as well as any other information which will benefit the proposal.

BUSINESS PROPOSAL – TABLE OF CONTENTS

SECTION 1 – PROPOSAL COVER SHEET (use form NIH 2043 identified in Section J of the solicitation)

SECTION 2 – COST OR PRICE SUPPORT

Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in a clearly marked section of the proposal.
SECTION 3 – UNIFORM COST ASSUMPTIONS

1) **Technical Cost Assumptions**

Assume costs associated with SDMCC support of Statistical Design and Analyses, Data Management and Analyses, and Program Coordination Services for the following CIVICs program activities:

1. Manufacturing, formulation and delivery of two (2) cGMP-grade influenza vaccine candidates in the first year.
2. IND-enabling safety and toxicity testing of four (4) influenza vaccine candidates in the first year.
3. Detailed immunologic analyses of the above influenza vaccine candidates in animal models in the first year.
4. Detailed immunologic analyses of human samples from clinical trials of influenza vaccine candidates in the second year.
5. Establishment of a clinical sample repository within the Clinical Core, and design and planning activities for future clinical trials and human challenge studies in the first year.
6. Conduct of two (2) Phase I clinical trials in the second year; conduct of one (1) Phase II clinical trial in the second year; and conduct of one (1) human challenge study in the second year. For the purposes of these cost assumptions, the Phase II clinical trials should include no more than 200 subjects and the human challenge studies should include no more than 200 subjects.
7. Audits: Assume two (2) independent QA audits for the duration of the contract period of performance.

2) **Travel**

A. *Contract Initiation Meeting:* Assume one meeting in Bethesda, Maryland within three months after the effective date of the contract to discuss contract initiation. Assume that this meeting will require a two-night stay and shall be attended by all of the Contractor’s key personnel.
B. **Training Workshops**: Assume 4 one-day training workshops per year for clinical site staff, to be held in the Bethesda, Maryland area, each requiring 4 presenters, including Contractor/subcontractor staff and consultants.

C. **Site visits to CIVICs contractor sites**: The Contractor shall be responsible for arranging a one-day meeting at each CIVICs prime contractor site. Attendees should include all Key Personnel and Key Subcontractor personnel.

D. **Annual Contract Programmatic Meetings**: For each year of performance, the Contractor shall attend an Annual Contract Review meeting. The meetings will be held at one of the CIVICs program contractor’s facility, and/or a location at or near Washington D.C., on an alternating-year basis. Attendees should include all Key Personnel and Key Subcontractor personnel.

3) **Special Shipping and Packaging**

*Not applicable*

4) **Storage**

*Not applicable*

5) **Government Furnished Property**

- Government Furnished Property is offered for this acquisition.
- No Government Furnished Property is offered for this acquisition.
The purchase of Government Furnished Property will not be authorized as a direct charge under the resultant contract.

**SECTION 4 – OPTIONS**

**Option 1 - 6: Extend the Term of the Contract:** The Government may include options to extend the period of the performance. The total period of performance resulting from the base period plus all potential Term Options is seven [7] years. If Option 1-6 are exercised, the services required will be the same as provided during the base year.

**Option 7 - 41: Increase Level of Effort:** The Government may exercise options for increased level of effort that may result from unanticipated increases in demand, as the CIVICs program activities increase. Should the Government elect to exercise these options, the Contractor shall provide resources for the unanticipated increase in work volume by half [0.5] FTEs for each option exercised, with a maximum of five (5) options (i.e., 2.5 additional FTEs) being exercised in the base year and in each option year thereafter.

**SECTION 5 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION**

Refer to Section L of the solicitation for documentation requirements. All relevant documentation should be included in a clearly marked section of the proposal.
ATTACHMENT 6: REPORTING REQUIREMENTS AND DELIVERABLES

CIVICs Statistical, Data Management and Coordination Center (SDMCC)
RFP-NIAID-DAIT-NIHAI201800018

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Reports

☐ (1) Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

☒ (2) Quarterly Progress Report

(a) This report shall include a summation of the Monthly Progress Reports and a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full three months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months.

(b) A Monthly Progress Report will not be submitted for the final month of a quarter.

☐ (3) Semi-Annual Progress Report
(a) This report shall include a summation of the Monthly Progress Reports and a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The initial report will be submitted for the first full six months of the contract performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of six full calendar months.

(b) Monthly and Quarterly Progress Reports will not be submitted the month the Semi-Annual Progress Report is due.

(4) Annual Progress Report

This report includes a summation of the results of the entire contract work for the period covered. An Annual Progress Report will not be required for the period when the Final Report is due. A Monthly Quarterly Semi-Annual Progress Report shall not be submitted when an Annual Progress Report is due.

The Contractor shall provide the Contracting Officer’s Representative and Contracting Officer with copies of the Annual Progress Report in draft form in accordance with the DELIVERIES Article in SECTION F of this contract [Insert Number] calendar days prior to the delivery date for the Final Version of the Annual Progress Report. The Contracting Officer’s Representative will review the draft report and provide the Contracting Officer with comments within calendar days after receipt. The Annual Progress Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

(5) Annual Technical Progress Report for Clinical Research Study Populations

(6) Final Report
☐ This report is to include a summation of the work performed and the results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. A/An [☐ Annual ☐ Semi-Annual ☐ Quarterly ☐ Monthly] Progress Report will not be required for the period when the Final Report is due.

☒ This report shall consist of the work performed and results obtained for the entire contract period of performance as stated in SECTION F of this contract. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted on or before the last day of the contract performance period. A/An [☒ Annual ☐ Semi-Annual ☐ Quarterly ☐ Monthly] Progress Report will not be required for the period when the Final Report is due.

☒ The Contractor shall provide the Contracting Officer’s Representative and Contracting Officer with [1] copy of the Final Report in draft form [☐ in accordance with the DELIVERIES Article in SECTION F of this contract ☒ [90] calendar days prior to the completion date of this contract.] The Contracting Officer’s Representative will review the draft report and provide the Contracting Officer with comments within [30] calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

☒ (7) Summary of Salient Results.

The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

☐ (8) Report on Select Agents or Toxins and/or Highly Pathogenic Agents
REPORTS AND DELIVERABLES

☐ Human Subjects IRB Annual Report (Form OMB No. 0990-0263-formerly Optional Form 310)

☒ Information Security and Physical Access Reporting Requirements - Use when the Information and Physical Access Security Article is required in Section H of the contract.

☒ Section 508 Annual Report - Use in multiple year solicitations and contracts over the simplified acquisition threshold which contain the Electronic and Information Technology Accessibility Article in Section H of the contract.

☒ Source Code and Object Code - Use when software is used, produced, modified or enhanced.

☒ Invention Report Requirement - Use when Patent Rights clause (FAR 52.227-11 or 52.227-13) may be included in the contract.

SECTION D – PACKAGING, MARKING, AND SHIPPING

☒ Special packaging, marking and shipping specifications are NOT required.
All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

☐ Special packaging, marking and shipping specifications are required.

ARTICLE D.1. PACKAGING

ARTICLE D.2. MARKING

ARTICLE D.3. SHIPPING

ARTICLE F.3 – DELIVERIES

a. Technical Progress Reports

<table>
<thead>
<tr>
<th>Item</th>
<th>Reports</th>
<th>Recipients</th>
<th>Delivery Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Quarterly Progress Report</td>
<td>1 electronic copy to COR and CO</td>
<td>The first report is due on/before the first full 3 months. Thereafter, the reporting period shall consist of three full calendar months. Each report is due on/before the 30th of the month following each reporting period.</td>
</tr>
<tr>
<td>2.</td>
<td>Annual Progress Report</td>
<td>1 electronic copy to COR and CO</td>
<td>The first report is due on the anniversary date of the contract. Thereafter, each report is due on/before the 30th of the month following each anniversary date of the contract. Quarterly Progress Reports will not be submitted the month the Annual Progress Report is due.</td>
</tr>
<tr>
<td>Item</td>
<td>Reports</td>
<td>Recipients</td>
<td>Delivery Schedule</td>
</tr>
<tr>
<td>------</td>
<td>---------</td>
<td>------------</td>
<td>------------------</td>
</tr>
<tr>
<td>3.</td>
<td>Annual Utilization Report</td>
<td>1 electronic copy to CO</td>
<td>Due on/before the 30th of the month following each anniversary date of the contract.</td>
</tr>
<tr>
<td>4.</td>
<td>Final Invention Statement</td>
<td>1 electronic copy to CO</td>
<td>Due on/before completion date of the contract.</td>
</tr>
<tr>
<td>5.</td>
<td>All reports and documentation including the invention disclosure report, the confirmatory license, and the government support certification</td>
<td>1 copy to OPERA</td>
<td>As required by FAR Clause 52.227-11.</td>
</tr>
</tbody>
</table>
| 6.   | Draft Final and Final Report and Summary of Salient Results | 1 electronic copy to COR and CO | Draft Final Report is due __90__ calendar days prior to the completion date of contract.  
Final Report is due on/before the completion date of the contract. |

**b. Other Reports and Deliverables (Delivery Schedule)**

<table>
<thead>
<tr>
<th>Item</th>
<th>Deliverables</th>
<th>SOW Reference</th>
<th>Recipient</th>
<th>Delivery Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>SOP and other manuals described in the SOW</td>
<td>Entire SOW</td>
<td>1 elec. copy to COR and CO, and other NIAID staff designated by the COR.</td>
<td>Determined with COR, CO and other NIAID staff (as designated by the COR) during pre-award negotiations</td>
</tr>
<tr>
<td>2.</td>
<td>Draft Entity Relational Diagrams, Use Cases and Graphical User Interface for the SDMCC Portal</td>
<td>3. CIVICs Program Data Access and Resource Sharing.</td>
<td>1 elec. copy to COR and CO, and other NIAID staff designated by the COR.</td>
<td>45 calendar days after contract award</td>
</tr>
<tr>
<td>Item</td>
<td>Deliverables</td>
<td>SOW Reference</td>
<td>Recipient</td>
<td>Delivery Schedule</td>
</tr>
<tr>
<td>------</td>
<td>--------------</td>
<td>---------------</td>
<td>-----------</td>
<td>------------------</td>
</tr>
<tr>
<td>3.</td>
<td>Quality Management Reports</td>
<td>3.c  CIVICs Program Data Access and Resource Sharing</td>
<td>1 elec. copy to COR and CO, and other NIAID staff designated by the COR.</td>
<td>Include as an appendix to all Quarterly and Annual Technical Progress Reports and on an ad hoc basis two (2) weeks following CO/COR request</td>
</tr>
<tr>
<td>5.</td>
<td>Source Code for all statistical and/or data analysis tools developed by the Contractor</td>
<td>1.b. Statistical Analysis; 2. Data Management and Analysis</td>
<td>1 elec. copy to COR and CO, and other NIAID staff designated by the COR.</td>
<td>60 days prior to contract completion</td>
</tr>
<tr>
<td>6.</td>
<td>Source Code and all documentation used in development of the SDMCC data management system and portal</td>
<td>Entire SOW</td>
<td>1 elec. copy to COR and CO, and other NIAID staff designated by the COR.</td>
<td>60 days prior to contract completion</td>
</tr>
<tr>
<td>7.</td>
<td>All information contained in the SDMCC data management system, including metadata, data, Protocols, reagent and preclinical/clinical sample information etc.</td>
<td>Entire SOW</td>
<td>1 elec. copy to COR and CO, and other NIAID staff designated by the COR.</td>
<td>60 days prior to contract completion</td>
</tr>
</tbody>
</table>